IN THE UNITED STATES BANKRUPTCY COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

In re: TEHUM CARE SERVICES, INC., Debtor.	Case No. 23-90086 (CML) (Chapter 11)

MOTION FOR LIMITED RELIEF FROM THE AUTOMATIC STAY BY REUBEN CORTES Individually AND AS CLASS REPRESENTATIVE, AND HEARN LAW, PLC. AS CLASS COUNSEL IN CORTES, et al., v. JOSH TEWALT, et al., PENDING IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF IDAHO, CASE NO. 1:18 -cv-00001-BLW

IF YOU OBJECT TO THE RELIEF REQUESTED, YOU MUST RESPOND IN WRITING. UNLESS OTHERWISE DIRECTED BY THE COURT, YOU MUST FILE YOUR RESPONSE ELECTRONICALLY AT HTTPS://ECF.TXSB.USCOURTS.GOV/ WITHIN TWENTY-ONE DAYS FROM THE DATE THIS MOTION WAS FILED. IF YOU DO NOT HAVE ELECTRONIC FILING PRIVILEGES, YOU MUST FILE A WRITTEN OBJECTION THAT IS ACTUALLY RECEIVED BY THE CLERK WITHIN TWENTY-ONE DAYS FROM THE DATE THIS MOTION WAS FILED. OTHERWISE, THE COURT MAY TREAT THE PLEADING AS UNOPPOSED AND GRANT THE RELIEF REQUESTED.

A HEARING WILL BE CONDUCTED ON THIS MATTER ON AUGUST 3, 2023, AT 10:00 A.M. CT IN COURTROOM 401, 515 RUSK ST., HOUSTON, TX 77002. YOU MAY PARTICIPATE IN THE HEARING EITHER IN PERSON OR BY AN AUDIO AND VIDEO CONNECTION.

AUDIO COMMUNICATION WILL BE BY USE OF THE COURT'S DIAL-IN FACILITY. YOU MAY ACCESS THE FACILITY AT 832-917-1510. ONCE CONNECTED, YOU WILL BE ASKED TO ENTER THE CONFERENCE ROOM NUMBER. JUDGE LOPEZ'S CONFERENCE ROOM NUMBER IS 590153. VIDEO COMMUNICATION WILL BE BY USE OF THE GOTOMEETING PLATFORM. CONNECTION VIA THE FREE GOTOMEETING APPLICATION OR CLICK THE LINK ON JUDGE LOPEZ'S HOME PAGE. THE MEETING CODE IS "JUDGELOPEZ." CLICK THE SETTINGS ICON IN THE UPPER RIGHT CORNER AND ENTER YOUR NAME UNDER THE PERSONAL INFORMATION SETTING.

HEARING APPEARANCES MUST BE MADE ELECTRONICALLY IN ADVANCE OF BOTH ELECTRONIC AND IN-PERSON HEARINGS. TO MAKE YOUR APPEARANCE, CLICK THE "ELECTRONIC APPEARANCE" LINK ON JUDGE LOPEZ'S HOMEPAGE. SELECT THE CASE NAME, COMPLETE THE REQUIRED FIELDS, AND CLICK "SUBMIT" TO COMPLETE YOUR APPEARANCE.

The Class of Idaho Department of Corrections Inmates and their attorneys of record, by and through their undersigned counsel, submits this motion ("Motion") seeking the entry of an order substantially in the form attached hereto as **Exhibit A** ("Proposed Order") lifting the automatic stay for cause under 11 U.S.C. § 362(d)(1) for the limited purpose of authorizing the United States District Court for the District of Idaho (the "Idaho District Court") to determine whether to approve an amended settlement agreement of a class action suit brought by a group of Idaho Department of Correction inmates (the "Class" or the "IDOC Inmates") against officials of the Idaho Department of Corrections ("IDOC") and Debtor Corizon, Inc. n/k/a Tehum Care Services Inc. ("Debtor"). In support of this Motion, the Class and class counsel respectfully represent as follows:

Jurisdiction, Venue, and Statutory Predicates

1. The U.S. Bankruptcy Court for the Southern District of Texas ("Court") has jurisdiction to consider this Motion under 28 U.S.C. §§ 157 and 1334 and *General Order 2012-6* issued by the U.S. District Court for the Southern District of Texas, *In re Order of Reference to Bankruptcy Judges* (S.D. Tex. May 12, 2012).

2. This matter is a core proceeding under 28 U.S.C. § 157(b)(2)(G).

3. Venue in this district is proper under 28 U.S.C. §§ 1408-09.

4. The Court is authorized to grant the requested relief under 11 U.S.C. § 362(d)(1); Rules 4001(a) and 9014 of the Federal Rules of Bankruptcy Procedure ("Bankruptcy Rules"); Rule 4001-1 of the Bankruptcy Local Rules of this Court ("Local Rules"); and Procedure 16 of the Procedures for Complex Cases in the Southern District of Texas ("Complex Case Procedures").

Background

5. In January, 2018, several IDOC inmates who had or were suffering from Hepatitis C Virus ("HCV") commenced an action by the filing of a Complaint in the United States District Court for the District of Idaho as case no. 1:18-cv-00001-BLW (the "District Court Action").[1] HCV is a serious and life-threatening disease which had become curable following the development and FDA approval of direct acting antiviral medications known as "DAAs". The Complaint sought declaratory, injunctive, and monetary relief based on allegations of inadequate medical care and treatment for HCV in violation of their federal constitutional right to adequate medical care under the Eighth Amendment from IDOC and the Debtor (as Corizon), which, at that time, was under contract with the IDOC to provide healthcare services to IDOC inmates.[2] The Hearn Law firm in Pocatello, Idaho, appeared for the plaintiffs in July, 2018, and by way of amended and supplemental complaints eventually there were 124 named Plaintiffs, 89 of which asserted individual claims for monetary damages against only Corizon, Inc. (later Corizon LLC) and three of Corizon's health care providers (hereafter "Corizon" or "Corizon defendants" collectively). In addition to the monetary damage claims against the Corizon defendants only, class action claims for declaratory and injunctive relief were pleaded against the IDOC and Corizon defendants.

6. In October, 2018, Plaintiffs moved for class certification and for a preliminary injunction/temporary restraining order, followed by a motion for partial summary judgment, all relating to the claims for declaratory and injunctive relief. While these motions were pending, the

[1] Complaint, Case No. 1:18-cv-00001-BLW (D. Idaho filed January 3, 2018), Dkt. No. 11.

[2] On Sept. 30, 2021 the contractual relationship between IDOC and Corizon ended

District Court ordered a case management conference. As a result of that conference, the parties were ordered to engage in alternative dispute resolution proceedings (mediation). Multiple formal mediation sessions and extensive informal negotiations between July, 2019 and May, 2020 resulted in agreement on all material substantive terms regarding settlement of the equitable claims for declaratory and injunctive relief. As discussed further below, it is this settlement that is the subject of this motion for partial relief from the stay.

7. The parties then concentrated mostly on resolution of the monetary damage claims against the Corizon defendants. Again, following several formal mediation sessions and extensive informal negotiations, on November 25, 2020 the parties agreed to a settlement of all the individual damage claims asserted in the litigation against the Corizon defendants. In a joint status report to the Idaho District Court on December 30, 2020, the parties advised the Court that a global resolution of all claims in the case had been reached subject to finalization of the settlement and release documents. By July, 2021, all named plaintiffs with individual damage claims against the Corizon defendants had each executed a separate Settlement Agreement and Release which were all delivered to Corizon's attorneys. A stipulation to dismiss the individual damage claims was prepared and then filed by Corizon's attorneys on August 31, 2021. By Order entered on February 4, 2022, the District Court granted the parties' stipulation for dismissal of all the monetary damage claims [3], and also entered a Rule 54 (b) Judgment dismissing those damage claims with prejudice.[4]

[3] Order Severing Claims of Plaintiff Joseph Williams into a Separate Case; order granting Stipulation for Dismissal of All Other Plaintiffs Claims for Damages, Case No. 1:18-cv-00001-BLW (D. Idaho filed February 4, 2022), Dkt. No. 131.

[4] Rule 54(b) Judgment, Case No. 1:18-cv-00001-BLW (D. Idaho filed February 4, 2022), Dkt. No. 132.

This left for final resolution only the parties settlement agreement and release respecting the equitable claims for injunctive relief, which is the subject of the instant motion.

8. The parties' settlement agreement of the injunctive relief claims was executed by IDOC's director (Josh Tewalt) on August 3, 2021, by Corizon, LLC (J. Scott King) on August 18, 2021, and by Plaintiffs' attorneys (Hearn and Ingelstrom) on August 19, 2021. The agreement was entitled "Private Settlement Agreement and Release" and expressly specified it was to be deemed a private settlement in accordance with 18 U.S.C. §3626(c)(2). It called for the certification of a FRCP 23(b)(2) class for injunctive relief and for settlement purposes only under FRCP 23(e). As such, the settlement agreement was required to be approved by the District Court. FRCP 23(e). Because it would be binding upon the unnamed class members, the court could approve it only upon finding it to be fair, reasonable and adequate. FRCP 23(e)(2). This requirement is not for the protection of the settling defendants or the class representatives, but rather for the protection of the entire class membership.

9. A Joint Motion for Preliminary Approval of Class Action Settlement and a Memorandum in Support thereof were prepared and filed by counsel for the Corizon defendants on August 31, 2021. The motion and supporting documents sought preliminary approval of the settlement; certification of a class for settlement purposes consisting of over 8,000 inmates in IDOC custody and all inmates entering IDOC custody during the term of the Agreement; appointment of Plaintiffs' attorneys (Hearn Law, PLC) as class counsel; directing notice to the class; and giving final approval of the proposed settlement agreement.[5]

[5] Joint Motion for Preliminary Approval of Class Action Settlement, Case No. 1:18-cv-00001-BLW (D. Idaho filed August 31, 2021), Dkt. No. 127.

10. The proposed settlement agreement was attached as Exhibit 1 to the supporting memorandum.[6] The supporting memorandum addresses several of the key provisions of the Agreement, including: (1) universal testing for HCV on an opt-out basis; (2) treatment eligibility and protocols; (3) IDOC's obligation to spend a specified amount in each of the first five (5) fiscal years covered by the Agreement, for a total of $29.25 million, exclusively for providing DAA treatment to inmates; (4) education of inmates with HCV released without receiving DAA treatment, including references and resources for how and where to obtain treatment in the community and options for payment; (5) documentation requirements for compliance monitoring by class counsel during the term of the Agreement; (6) fair and reasonable attorney fees and costs for Plaintiff's attorneys; (7) enforcement provisions in the event of a breach; and (8) dismissal of the action and release of claims.

11. In January 2022, the Court entered an "Order Requiring Clarification" having determined it needed additional information.[7] There, the Court observed as follows: "As to the subject matter of the Settlement Agreement, the Court agrees that settlement of the disputed issue of a clear protocol for delivering HCV diagnostic care and treatment for all IDOC inmates, present and future, is an important singular, and severable issue from individual inmate claims for damages. If three years of negotiations has produced only a fair, reasonable, and adequate proposal for declaratory and injunctive relief, then that work product is worthy of preservation and

[6] Private Settlement Agreement and Release, Case No. 1:18-cv-00001-BLW (D. Idaho filed August 31, 2021). Dkt. No. 127-2.
[7] Order Requiring Clarification, Case No. 1:18-cv-00001-BLW (D. Idaho filed January 6, 2022), Dkt. No. 129.

implementation on behalf of all inmates."[8] The attorneys for the Corizon defendants then prepared and on January 21, 2022, filed the Joint Response to Order Requiring Clarification.[9]

12. On February 8, 2022, the Idaho District Court entered an Order giving preliminary approval of the Settlement Agreement pertaining to the injunctive relief claims, certifying a class for settlement purposes, appointing Richard A. Hearn and John B. Ingelstrom of Hearn Law PLC as class counsel, appointing Reuben Cortes as class representative, directing notice to the class including class member's rights to objection, and scheduling the fairness hearing on May 10, 2022.[10]

13. By Order entered on September 29, 2022, the District Court denied final approval of the Settlement "…with the hope that the parties will make adjustments to their agreement and resubmit it in the near future." The main issues the Court identified for withholding final approval are as follows: (a) confusion over the nature of the future claims (those arising during the term of the Agreement) being released and the eligibility of all inmates for DAA treatment regardless of risk classification; (b) refinement of the class definition to include only those in physical custody and not those on probation or parole; and (c) to address a Federal Bureau of Prisons (FBOP) standard referenced in the treatment protocol provisions of the Agreement that had changed "[w]hile the Settlement Agreement was awaiting class certification and final approval, not due to the fault of the parties…"

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[8] Order Requiring Clarification, Case No. 1:18-cv-00001-BLW (D. Idaho filed January 6, 2022), Dkt. No. 129 Pg 3-4.

[9] Joint Response to Order Requiring Clarification, Case No. 1:18-cv-00001-BLW (D. Idaho filed January 21, 2022), Dkt. 130.

[10] Order Approving Settlement Proposal and Certifying a Class for Settlement of declaratory and injunctive Relief Claims, Case No. 1:18-cv-00001-BLW (D. Idaho filed February 8, 2022), Dkt. 134.

14. Thereafter the parties agreed to negotiate modifications to address the District Court's reservations about giving final approval to the Settlement. Those efforts resulted in an Amended Private Settlement Agreement and Release. That Amended Agreement was executed by the parties on December 1, 2022, with Corizon, LLC reconfirming its commitment to the settlement by the signature of Isaac Lefkowitz, Senior Vice President on behalf of Corizon, LLC. Attorneys for the Corizon defendants authorized the affixation of their signature on the Memorandum in Support of Joint Motion for Final Approval of Amended Class Action Settlement, filed on December 2, 2022.[11] The Amended Settlement Agreement was filed with the supporting memorandum.[12] A Copy of the Amended Private Settlement Agreement and Release (the Amended Settlement Agreement") is attached hereto as **Exhibit B**. However, while the matter was pending the District Court's determination of whether to give final approval to the Amended Settlement, on February 13, 2023, Tehum (Corizon) filed its voluntary petition for relief under Chapter 11,[13] and filed a Suggestion of Bankruptcy and Notice of Automatic Stay in the Idaho District Court Action.[14] Accordingly, for more than 5 ½ years after the filing of the class action and nearly two years after the parties executed the initial settlement agreement: (a) over 8000 current inmates in IDOC custody and all those who will become inmates before June 30, 2028, still have no enforceable rights to the constitutionally adequate medical care of HCV specified in

[11] Memorandum in Support of Joint Motion for Final Approval of Amended Class Action Settlement, Case No. 1:18-cv-00001-BLW (D. Idaho filed December 2, 2022), Dkt. No. 170.

[12] Amended Private Settlement Agreement and Release, Case No. 1:18-cv-00001-BLW (D. Idaho filed on December 2, 2022), Dkt. No. 170-1.

[13] Docket No. 1

[14]Suggestion of Bankruptcy and Notice of Automatic Stay, Case no. 1:18-cv-00001-BLW (D. Court filed February 21, 2023), Dkt. No. 171.

the Amended Settlement Agreement; (b) Plaintiffs' attorneys and class counsel have received no compensation for the legal services rendered over the past five (5) years and no reimbursement of costs incurred in the representation; and (c) the class action lawsuit remains open on the Idaho District Court's docket.

15. Because Corizon is no longer the contracted health care provider for IDOC, there are only three provisions in the Amended Private Settlement Agreement and Release that are relevant to Tehum (Corizon) and this motion for limited relief from the automatic stay:

(a) Paragraph 3.8, Attorney Fees and Costs "…the Parties further agree that Corizon, LLC is only responsible to pay (and agrees to pay) $27,421.22 in costs and $100,000.00 in attorney fees, which payment is due and payable within thirty (30) days from the Effective Date of the Agreement." (parenthetical in original). The rest and remainder of class counsel's fair and reasonable attorney fees and costs will be determined by the Idaho District Court and payable from the fund represented by IDOC's required expenditures for DAA treatment under Paragraph 3.6 of the Agreement, which expenditures are, of course, derived from appropriations by the Idaho Legislature. The class and class counsel seek stay relief allowing them to file their petition for fees and costs from IDOC's expenditure fund and the Idaho District Court to determine such fair and reasonable fees and costs. Respecting Tehum's/Corizon's specified portion of the fees and costs, the class and class counsel recognize and commit to seek recovery of the same only through the claim procedures in this Bankruptcy Court (unless debtor's petition is dismissed).

(b) Paragraph 3.11, Dismissal of Defendants. Provides for the dismissal with prejudice of all claims in the Operative Complaint against the Corizon defendants by the filing within 14 days of the

Effective Date of the Agreement a Stipulation for Dismissal with Prejudice. The class and class counsel also seek stay relief to file said stipulation.

(c) Paragraph 3.12, Release of Claims Against Defendants.

16. Movants are mindful that there may be a possible indemnification claim by IDOC against Tehum/Corizon. However, no such claim has been asserted in the Idaho class action lawsuit. Movants are unaware of any such claim that has been filed in any other courts in Idaho. It is also clear that any such claim by IDOC would have already accrued and that it would be subject to the automatic stay. This motion does not seek stay relief with respect to any such claim by IDOC, which claim would necessarily have to be made in Tehum's bankruptcy case. Further, there is nothing about the instant motion for limited relief from the stay which adversely effects or otherwise prejudices the rights of Tehum/Corizon with regard to any indemnity claim IDOC may wish to assert in this Bankruptcy Court arising out of the Idaho class action litigation.

Relief Requested

17. By this Motion, the Class seeks the entry of the Proposed Order lifting the automatic stay for cause under 11 U.S.C. § 362(d)(1) for the limited purposes of (a) permitting the Idaho Federal District Court to determine whether to approve the Amended Settlement Agreement, (b) if the Idaho District Court approves the Amended Settlement Agreement, allowing class counsel to petition the District Court and that Court to determine fair and reasonable attorney fees and costs in accordance with ¶ 3.8 of the Settlement Agreement discussed above; and (c) if the Agreement is approved allowing counsel to file a stipulation for dismissal of the claims Against Corizon, and for the Court to enter a dismissal order thereon.

Basis for Requested Relief

A. Legal Standard

18. Section 362(d)(1) of the Bankruptcy Code provides:

> (d) On request of a party in interest and after notice and a hearing, the court shall grant relief from the stay provided under [§ 362(a)], such as by terminating, annulling, modifying, or conditioning such stay –
>
> (1) for cause, including the lack of adequate protection of an interest in property of such party in interest . . .

19. The moving party bears the initial burden of establishing "a *prima facie* case for relief," while "the party opposing stay relief . . . has the ultimate burden of persuasion (or the risk of non-persuasion)."[15]

20. "Cause is an intentionally broad and flexible concept, made so in order to permit the courts to respond in equity to inherently fact-sensitive situations."[16] Because the statute does not define "cause," courts determine its existence "on a case by case basis based on an examination of the totality of circumstances."[17] In a report on the Bankruptcy Reform Act of 1978 issued shortly before its enactment, the House of Representatives Committee on the Judiciary provided the following guidance on cause:

> The lack of adequate protection of an interest in property of the party requesting relief from the stay is one cause for relief, but it is not the only cause. . . . [A] desire to permit an action to proceed to completion in another tribunal may provide

[15] *In re Rogers*, 239 B.R. 883, 887 (Bankr. E.D. Tex. 1999).

[16] *Mooney v. Gill*, 310 B.R. 543, 547 (N.D. Tex. 2002) (internal quotation marks and citation omitted).

[17] *In re WGMJR, Inc.*, 425 B.R. 423, 433 (Bankr. S.D. Tex. 2010; *see also In re Omni Lion's Run, LP*, 578 B.R. 394, 398 (Bankr. W.D. Tex. 2017)

another cause. . .. The facts of each request will determine whether relief is appropriate under the circumstances."[18]

21. Courts in the Fifth Circuit "apply a variety of factor-based tests" to assess the totality of the circumstances, and "no single approach prevails."[19] Some Courts apply the following 12-factor test ("*Curtis* Factors") when a movant seeks stay relief to continue proceeding in a non-bankruptcy forum:

1. Whether the relief will result in a partial or complete resolution of the issues;

2. The lack of any connection with or interference with the bankruptcy case;

3. Whether the foreign proceeding involves the debtor as a fiduciary;

4. Whether a specialized tribunal has been established to hear the particular cause of action and that tribunal has the expertise to hear such cases;

5. Whether the debtor's insurance carrier has assumed full financial responsibility for defending the litigation;

6. Whether the action essentially involves third parties and the debtor functions only as a bailee or conduit for the goods or proceeds in question;

7. Whether litigation in another forum would prejudice the interest of other creditors, the creditors' committee, and other interested parties;

8. Whether the judgment claim arising from the foreign action is subject to equitable subordination under Section 510(c);

9. Whether the movant's success in the foreign proceeding would result in a judicial lien avoidable by the debtor under Section 522(f);

10. The interest of the judicial economy and the expeditious and economical determination of litigation for the parties;

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[18] H.R. Rep. No. 95-595, at 343-44 (1978); *see also In re Fowler*, 259 B.R. 856, 858 (Bankr. E.D. Tex. 2001); and *In re Xenon Anesthesia of Texas, PLLC*, 510 B.R. 106, 112 (Bankr. S.D. Tex. 2014) (finding that allowing a matter to proceed in another forum may constitute cause).

[19] *In re White*, No. 18-50385, 2018 WL 4677440, at *6 (Bankr. S.D. Miss. Sept. 27, 2018) (internal quotation marks and citation omitted).

11. Whether the foreign proceedings have progressed to the point where the parties are prepared for trial; and

12. The impact of the stay on the parties and the balance of the hurt.[20]

Courts "should only apply the factors that are relevant to the case and do not need to give each factor equal weight."[21]

22. By contrast, some courts have recognized that "the decision to lift the stay may be upheld on judicial economy grounds alone."[22] Another court conditioned cause on just two requirements: "(a) [n]o 'great prejudice' to either the bankruptcy estate or the debtor must result from the continuance of the civil action, and (b) the hardship to the plaintiff caused by the continuance of the stay considerably outweighs the hardship caused to the debtor by modification of the stay."[23]

23. The "common denominator" among all the tests "is [their] focus on the policies underlying the Bankruptcy Code as well as the competing interests of the creditor, debtor, and other parties in interest."[24]

B. Cause Exists to Grant the Requested Relief.

24. The totality of the circumstances and the applicable *Curtis* Factors support this request for limited stay relief.[25] Under any test, the balance of the harms weighs heavily against

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[20] *See, e.g., In re Armstrong & Guy Office, LLC*, No. 07-02459, 2007 WL 4571152, at *2 (Bankr. S.D. Miss. Dec. 11, 2007) (quoting *In re Curtis*, 40 B.R. 795, 799-800 (Bankr. D. Utah 1984)); *In re McConathy*, No. 90-13449, 2021 WL 2405734, at *7 (Bankr. W.D. La. June 14, 2021); *In re Xenon*, 510 B.R. at 112 (Bankr. S.D. Tex. 2014).

[21] *McConathy*, 2021 WL 2405734, at *7.

[22] *See, e.g., Xenon*, 510 B.R. at 112; *In re U.S. Brass Corp.*, 176 B.R. 11, 13 (Bankr. E.D. Tex. 1994).

[23] *Fowler*, 259 B.R. at 860 (quoting *In re McGraw*, 18 B.R. 140, 143 (Bkrtcy. W.D. Wis. 1982)).

[24] *White*, 2018 WL 4677440, at *6.

[25] The third, fourth, fifth, sixth, seventh, eighth, and ninth *Curtis* Factors are inapplicable.

the movants if the Idaho District Court's ability to approve the Amended Settlement remains stayed.

25. First, allowing the Idaho District Court Action to proceed will completely resolve the issues in the District Court Action.

26. Second, there will be minimal, if any, interference with the bankruptcy case because approval of the Amended Settlement Agreement will have no impact on the Debtor. The Debtor's only obligation under the Amended Settlement Agreement is its agreement to pay $100,000 toward Class counsel's attorney fees and $27,421.22 in costs. If the Idaho District Court approves the Amended Settlement Agreement, Debtor's obligation for payment of attorney fees and costs will be addressed through the claim procedures in the Bankruptcy Court. The Class further notes that the Debtor did not include the Idaho District Court Action among the lawsuits for which it obtained an emergency extension of stay.[26]

27. Third, allowing the Idaho District Court to consider approval of the Amended Settlement Agreement and its ultimate approval will not prejudice the other parties in interest. On the other hand, maintaining the stay could adversely impact the more than 8,000 inmates who are relying on the procedures and treatment protocols contained in the Amended Settlement Agreement to ensure they receive proper medical treatment. Since the Debtor is no longer the healthcare provider for IDOC it has no obligations to implement the agreed upon protocols or to provide medical treatment under the Amended Settlement Agreement.

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[26] *See* Order Regarding Debtor's Emergency Motion to Extend and Enforce the Automatic Stay, Case No. 23-90086, at Dkt. 118, Ex. 1.

28. Fourth, allowing the approval process in the Idaho District Court Action to continue would better serve the interests of judicial economy. If the stay remains in place, the Class's alternative is to seek approval of the Amended Settlement Agreement from this Court. The Idaho District Court is familiar with the facts and issues and has the benefit of specific experience with this proceeding since 2018. Addressing the issues in this Court will require this Court to expend judicial resources and result in the delay of a resolution and generate unnecessary expenses for all parties.

29. Fifth, the Class would suffer substantially more harm if the stay were not lifted than the Debtor would suffer if the Idaho District Court considers and rules on the approval of the Amended Settlement Agreement. As stated above, approval of the Amended Settlement Agreement has no monetary or other impact upon the Debtor. On the other hand, if the Amended Settlement Agreement is not approved, the Class could be denied lifesaving medical treatment.

WHEREFORE, the Class respectfully requests this Court enter the Proposed Order lifting the automatic stay for cause under 11 U.S.C. § 362(d)(1) for the limited purposes of (a) permitting the Idaho District Court to determine whether to approve the Amended Settlement Agreement, (b) if the Idaho District Court approves the Amended Settlement Agreement, allowing class counsel to petition the District Court and that Court to determine fair and reasonable attorney fees and costs in accordance with ¶ 3.8 of the Settlement Agreement discussed above; and (c) if the Agreement is approved, allowing counsel to file a stipulation for dismissal of the claims against Corizon, and for the Court to enter a dismissal order thereon.

DATED this 23rd day of June, 2023.

RACINE OLSON, PLLP

By: /s/ Daniel C. Green
DANIEL C. GREEN (Pro Hac Vice)

BLR 4001-1(a)(1) Certification

The undersigned hereby certifies that on April 4, 2023, he contacted the Debtor's counsel, by email to request the Debtor stipulate to limited relief from the automatic stay. I subsequently spoke with London England, one of Debtor's attorneys, concerning a proposed stipulation. Further email exchanges occurred on April 17, 2023 and April 24, 2023. In her April 24, 2023 email, Ms. England indicated the Debtor was still evaluating the request and would be in contact once a decision was reached. On May 5, 2023, a telephone conference was held between myself, John B. Ingelstrom, Richard Hearn, and Ms. England. In that telephone conference Ms. England advised us of her understanding that the IDOC intended to assert indemnification claims against Corizon arising out of the class action case. I further understand that it is the Debtor's position that it will not stipulate to stay relief if the relief does not resolve all potential indemnity claims.

/s/ Daniel C. Green
DANIEL C. GREEN

CERTIFICATE OF SERVICE AND CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 4001(a)(1)(4)

I HEREBY CERTIFY that a copy of this Motion was served on the persons shown on the service list attached hereto as **Exhibit C** via U.S. first-class mail, email, or CM/ECF as further indicated therein on the 23rd day of June, 2023, in compliance with Local Rule 4001(a)(1)(4).

/s/ Daniel C. Green
DANIEL C. GREEN

EXHIBIT A

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

In re: TEHUM CARE SERVICES, INC.,[1] Debtor.	Case No. 23-90086 (CML) (Chapter 11)

ORDER GRANTING MOTION FOR LIMITED RELIEF FROM THE AUTOMATIC STAY

The Class of Idaho Department of Corrections Inmates ("Movant") and their attorneys of record filed a motion for relief from the automatic stay ("Motion")[2] for the limited purpose of (a) permitting the Idaho Federal District Court to determine whether to approve the Amended Settlement Agreement, (b) if the Amended Settlement Agreement is approved, allowing class counsel to petition the Idaho Federal District Court and authorizing that court to determine fair and reasonable attorney fees and costs in accordance with paragraph 3.8 of the Amended Settlement Agreement, and (c) if the Amended Settlement Agreement is approved, authorizing counsel to file a stipulation for dismissal of the claims against Corizon, and for the court to enter a dismissal order. The Movant represented to the Court that it had served the motion in accordance with all applicable rules and provided notice of the hearing.

Although a response opposing the Motion was filed, the respondent did not appear at the hearing. Therefore, the

[1] The last four digits of the Debtor's federal Tax Identification Number are 8853. The Debtor's service address is: 205 Powell Pl., Ste. 104, Brentwood, TN 37027.

[2] Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Motion.

response is overruled for want of prosecution and the motion is granted.

_____ The Debtor filed a response that the Debtor was not opposed to the requested relief, and no other party opposed the requested relief.

_____ The Debtor filed a response that the Debtor was unable to admit or deny the allegations, the Debtor failed to appear at the hearing, and no other party opposed the requested relief.

_____ After hearing, and for the reasons stated on the record, relief from the stay is granted.

_____ No timely response was filed. Accordingly, the Motion is granted by default.

_____ As shown by the below signature of the Debtor's counsel, the Debtor has agreed to the requested relief.

The Class of Idaho Department of Corrections Inmates ("Movant") and their attorneys of record filed a motion for relief from the automatic stay ("Motion")[3] for the limited purpose of (a) permitting the Idaho Federal District Court to determine whether to approve the Amended Settlement Agreement, (b) if the Amended Settlement Agreement is approved, allowing class counsel to petition the Idaho Federal District Court and authorizing that court to determine fair and reasonable attorney fees and costs in accordance with paragraph 3.8 of the Amended Settlement Agreement, and (c) if the Amended Settlement Agreement is approved, authorizing counsel to file

[3] Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Motion.

a stipulation for dismissal of the claims against Corizon, and for the court to enter a dismissal order. The Movant represented to the Court that it had served the motion in accordance with all applicable rules and provided notice of the hearing.

Additional rulings:

_____ The Movant is awarded attorneys' fees in the amount of $_____.

_____ The stay imposed by Bankruptcy Rule 4001(a)(3) does not apply for the reasons stated on the record.

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

REUBEN CORTES, et al.,

Plaintiffs,

v.

JOSH TEWALT, et al.,

Defendants.

Case No.: 1:18-cv-00001-BLW

AMENDED PRIVATE SETTLEMENT AGREEMENT AND RELEASE

1. DEFINITIONS

1.1. "Action" shall refer to the above-captioned lawsuit filed in the United States District Court of Idaho, *Cortes, et al., v. Tewalt, et al.*, Case Number: 1:18-cv-00001-BLW.

1.2. "Agreement" shall refer to this Private Settlement Agreement and Release and all of the definitions, recitals, and terms and conditions contained herein.

1.3. "Chronic HCV" shall refer to the infection of an inmate who has a detectable HCV infection for a period of six (6) months.

1.4. "Class Counsel" shall refer to Richard A. Hearn and John B. Ingelstrom of Hearn Law, PLC, P.O. Box 70, Pocatello, Idaho, 83204, and any appropriately substituted attorney, who are the attorneys for the Individual Plaintiffs, Class Members, and the class to be certified by the Court for settlement purposes pursuant to FRCP 23(e).

1.5. "Class Members" shall refer to all current and future inmates in IDOC physical custody who have not been diagnosed with HCV regardless of their physical location; all current and future inmates in IDOC physical custody who have or will be diagnosed with HCV; and all Individual Plaintiffs who have been treated

with DAA Treatment. For purposes of this Agreement, Class Members shall include those persons comprising the class under FRCP 23(e) that the Parties agree to have the Court certify as a class for settlement purposes only. Class members shall include inmates in the physical custody of the IDOC but who are serving their sentences in facilities which are not part of the IDOC. Further, persons on parole or probation are not class members and not subject to the Agreement.

1.6. "Contractor" shall refer to any legal entity or person providing correctional healthcare by contract to IDOC inmates.

1.7. "Corizon Defendants" shall refer to the entity Corizon, LLC, and John G. Migliori, Murray F. Young, and April C. Dawson, in their official capacities, named as defendants in the Operative Complaint in this Action.

1.8. "Court" shall refer to the United States District Court for the District of Idaho in which the Action is filed and the presiding district judge who will be asked to certify a class inclusive of the Class Members, conduct the Fairness Hearing, provide Final Approval of this Agreement, and determine fair and reasonable attorney fees and costs.

1.9. "Court of Enforcement" shall refer to the Fourth Judicial District of the State of Idaho, in and for the County of Ada.

1.10. "DAA Medications" shall refer to the class of medications known as Direct-Acting Antivirals (DAA) used to treat HCV as of the Effective Date of this Agreement or approved for medical uses thereafter.

1.11. "DAA Treatment" shall refer to the process of evaluating inmates with HCV, routine monitoring and testing of inmates with HCV, procurement of DAA Medications, prescribing and administering DAA Medications to inmates with Chronic HCV, and post-DAA Medication monitoring.

1.12. "Defendants" shall refer collectively to the IDOC Defendants and Corizon Defendants.

1.13. "Effective Date" shall mean the date upon which the Court in this Action gives Final Approval to the Agreement.

1.14. "Eligibility" shall refer to all inmates with chronic HCV.

1.15. "Fairness Hearing" shall refer to the hearing before the Court pursuant to FRCP 23(e)(2) where the Parties will request that the Court enter an Order approving this Agreement as fair, reasonable, and adequate.

1.16. "Final Approval" shall refer to the Court's order granting final approval of this Agreement consistent with FRCP 23(e)(2) following the Fairness Hearing.

1.17. "FRCP" shall refer to the current version of the Federal Rules of Civil Procedure.

1.18. "HCV" shall refer to the viral infection known as the Hepatitis C virus.

1.19. "IDOC" shall refer to the Idaho Department of Correction, a department of the State of Idaho.

1.20. "IDOC Counsel" shall refer to the State of Idaho Deputy Attorney General appointed as the Lead Deputy Attorney General for IDOC. At the time of the execution of this Agreement, the Lead Deputy Attorney General for IDOC is Karin Magnelli.

1.21. "IDOC Defendants" shall refer to Josh Tewalt, Director of IDOC, substituted for former IDOC Director Henry Atencio, and Rona Siegert, IDOC's Health Services Director, in their official capacities, as well as their predecessors and any successors, whom shall be automatically substituted consistent with Rule 25(d) of the Federal Rules of Civil Procedure (FRCP).

1.22. "Individual Plaintiffs" shall refer to all of those individuals identified by name as plaintiffs in the Operative Complaint in this Action.

1.23. "Notice" shall refer to the notice to the class and Class Members of this Agreement prior to the Fairness Hearing.

1.24. "Operative Complaint" shall refer to the September 25, 2019, *Second Amended and Supplemental Complaint* filed in this Action and bearing Docket No. 111.

1.25. "Opt-Out Testing" shall refer to the policy and procedure implemented during the intake process for inmates entering the IDOC system to offer initial testing for the presence of HCV antibody and reflexive RNA HCV viral load; all inmates shall be tested for HCV unless the inmate signs a form refusing testing.

1.26. "Party" and "Parties" shall refer to and include the individuals, officers, and entities defined herein as IDOC Defendants, Corizon Defendants, Individual Plaintiffs, and Class Members, either collectively or each of them individually.

1.27. "Plaintiffs" shall refer to each of those Individual Plaintiffs as well as all current and future Class Members.

2. RECITALS

2.1. WHEREAS, Individual Plaintiffs filed this Action, on behalf of themselves and other similarly situated inmates who are currently and/or will in the future be in the custody of the IDOC, alleging that Defendants failed to provide universal and timely Opt-Out Testing and screening of inmates infected with HCV and failed to provide universal and timely treatment to HCV-positive inmates with DAA Treatment.

2.2. WHEREAS, the Parties, without conceding any infirmity in their claims or defenses, have engaged in extensive, arms-length settlement negotiations to resolve the claims raised in this Action, recognizing that it is in their mutual best interest to fully resolve and finally settle past, existing, and future claims for injunctive, declaratory, and equitable relief, as well as certain future claims for damages, between the Parties related to diagnosis, testing, evaluation, management, monitoring, education, and treatment of inmates with HCV.

2.3. WHEREAS, the Parties are entering into this Agreement solely and exclusively for settlement purposes and nothing contained in this Agreement shall be construed as an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Defendants expressly deny. Defendants do not admit to any wrongdoing that was or could have been alleged by the Plaintiffs and, in fact, Defendants (collectively and individually) deny any and all liability of any kind to Plaintiffs. Plaintiffs do not admit to any defense, either legal or factual, that was or could have been alleged by the Defendants. No part of this Agreement, including any exhibits, statements, or commitments, shall be construed as an admission or evidence of any liability, fault, or wrongdoing by Defendants. Except in any enforcement action filed in the Court of Enforcement, this Agreement shall not be admitted into evidence in any litigation other than this Action for the sole and exclusive purpose of settling this Action under FRCP 23(e). It is the intent of the Parties that this Agreement shall not create a

private cause of action or confer any right to any third party for violation of any federal or state statute, law, rule, or regulation.

2.4. WHEREAS, for settlement purposes only, the Parties agree that a class be certified pursuant to FRCP 23(b)(2) for settlement purposes only and that this Agreement be noticed and approved as to the Class Members in accordance with FRCP 23(e). It is neither the intent of the Parties, nor do the Parties agree, that the Court may certify a class for any other reason other than to obtain Final Approval of this Agreement pursuant to FRCP 23(e). Further, Defendants expressly reserve all defenses and arguments that it is inappropriate to certify a class for any other purpose, including but not limited to, certification of a class for monetary damages.

2.5. WHEREAS, the Parties reached the terms set forth below expressly based upon the agreement that this Agreement shall be deemed a private settlement agreement in accordance with 18 U.S.C. § 3626(c)(2) and not a consent decree, consent judgment, or other agreement whereby the Court retains jurisdiction to interpret, modify, or enforce the Agreement. Moreover, the Parties do not consent to the Court retaining jurisdiction and reach the terms and conditions in this Agreement expressly based upon the fact that the Court in approving this Agreement, shall not make any findings required by 18 U.S.C. § 3626 and, in the event the Court renders any such findings, this Agreement shall be null and void and unenforceable as a matter of law. In order to preserve the nature of this Agreement as a "private settlement agreement," the Parties further agree that, barring reinstatement of this Action pursuant to the terms of this Agreement, or the reversal or remand on appeal of the Court's Final Approval of this Agreement, and except for this Court's determination of fair and reasonable attorney fees and costs, this Court's jurisdiction will end with the approval of this Agreement and any proceedings pertaining to enforcement of this Agreement shall occur in the Court of Enforcement.

3. TERMS AND CONDITIONS

3.1. Opt-Out Testing at Intake: Defendants agree that at intake into an IDOC Reception and Diagnostic Unit ("RDU"), all inmates without a prior documented positive HCV RNA viral load test through IDOC shall be offered a HCV antibody test and, if the HCV antibody test is positive, a reflexive HCV RNA viral load test on an Opt-Out Testing basis. Contractor will provide all inmates at intake with a copy of the "Hepatitis C – General Information" form published by the Centers for Disease Control and Prevention, a copy of which is attached hereto as **Exhibit A**. In addition to Exhibit A, the Contractor is permitted to provide additional educational information regarding HCV to inmates at intake.

3.2. Post-Intake Testing: Defendants agree that inmates housed outside of an RDU without a prior documented positive HCV antibody test through IDOC will be tested within sixty (60) days upon written request submitted by the inmate on a Health Services Request form. IDOC Defendants shall provide notice of inmates' testing rights in the intake packet and by way of written notice posted in the facility. For a period of one (1) year from the Effective Date of this Agreement, inmates who have not yet been tested for HCV and have not submitted a written request on a Health Services Request form, shall be offered testing on an Opt-Out Testing basis during their first annual tuberculosis-screening visit following the Effective Date of this Agreement.

3.3. Chronic Disease Program: Defendants agree that inmates who are diagnosed with HCV will be enrolled in the Chronic Disease Program ("CDP") or its equivalent. IDOC will require that all inmates enrolled by Contractor in the CDP or its equivalent, before or while receiving DAA Treatment, will be evaluated on a regular basis to monitor health conditions related to HCV as deemed medically appropriate by Contractor's health providers. IDOC will also require the Contractor to evaluate, follow and treat inmates in a manner consistent with the current treatment recommendations established by the Federal Bureau of Prisons (FBOP) as may be deemed medically appropriate by the Contractor's health providers.

3.4. Hep C Log: While this Agreement is in effect, IDOC shall provide a written log to Class Counsel on a quarterly basis that includes the name, IDOC number, most recent APRI or F-Score, date of any subsequent determinations or assignments of APRI or F-Score, date treatment with DAA Medications was completed for IDOC inmates with HCV[1], and any other information required by the 2021, or most current, FBOP Clinical Guidance for the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection. The log shall also identify those inmates who refuse DAA Treatment. The log shall be provided to Class Counsel no later than January 15, April 15, July 15, and October 15 of each year and shall contain information current as of the last day of the preceding month. Each iteration of the log shall be marked "Confidential – Attorneys' Eyes Only" and Class Counsel shall maintain the confidentiality of the log pursuant to the Qualified Protective Order (Dkt. 107), entered in the Action on June 21, 2019. A Party is permitted to use

[1] Neither Corizon Defendants, IDOC Defendants nor any Contractor shall be obligated to provide the date of any APRI Score or F-Score assigned to or calculated for any inmate, or the date any inmate completed treatment with DAA Medications, prior to the date of production of the first Hep C Log produced to Class Counsel pursuant to section 3.4 of the Agreement.

the Hep C Log as is necessary in an action before the Court of Enforcement, but only so long as the individually identifiable health information of any Plaintiff, inmate, or other person protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) remains confidential and protected from disclosure to any person other than the Court and counsel of record. Consistent with the foregoing, the Hep C Log may be filed under seal with the Court of Enforcement and/or filed publicly with all redactions necessary to maintain the confidentiality of individuals' identifiable health information.

3.5. Eligibility for DAA Treatment: Defendants agree that all inmates with Chronic HCV are eligible to receive DAA treatment. DAA Treatment will be provided by the Contractor in a manner that is consistent with the March 2021 version, or most current, of the FBOP's Clinical Guidance for the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection. A copy of the 2021 FBOP's Clinical Guidance for the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection is attached hereto as **Exhibit B**. Notwithstanding the foregoing, the Contractor will be permitted to consult future treatment recommendations established by nationally-recognized authorities, such as the FBOP, The National Commission on Correctional Health Care, the National Institute of Health, the CDC and the AASLD/IDSA, and/or others, as deemed medically appropriate by the Contractor's health providers.

3.6. Expenditures and Treatment Obligations: IDOC Defendants agree to spend the following amounts exclusively for the purpose of providing DAA Treatment to all inmates with Chronic HCV:

3.6.1. $4.35 million for Fiscal Year (FY) 2021. Defendants are required to spend the allocated money to treat all-inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the annual fund has been exhausted.

3.6.2. $5.1 million for FY2022. Defendants are required to spend the allocated money to treat all-inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the annual fund has been exhausted.

3.6.3. $6.6 million for FY2023. Defendants are required to spend the allocated money to treat all inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the annual fund has been exhausted.

3.6.4. $6.6 million for FY2024. Defendants are required to spend the allocated money to treat all inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the annual fund has been exhausted.

3.6.5. $6.6 million for FY2025. Defendants are required to spend the allocated money to treat all inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the annual fund has been exhausted.

3.6.6. IDOC Defendants agree to continue the obligations set forth in paragraphs 3.1, 3.2, 3.3, 3.4, 3.5 and 3.7 in this Agreement during FY2026, FY2027, and FY2028, and will allocate sufficient funds for the purpose of providing DAA Treatment to all inmates with chronic HCV. The allocation will take into consideration the number of inmates in IDOC's physical custody with chronic HIV who have not yet been treated, the total number of HCV-positive inmates in IDOC's physical custody the prior year, the average cost of DAA Treatment, and other relevant factors. IDOC Defendants are required to spend the allocated money to treat all inmates with chronic HCV, beginning at the highest risk levels and descending to the lower risk levels until the allocated annual fund has been exhausted.

3.6.7. Provided, however, that nothing in this Agreement will prohibit IDOC Defendants from, in the IDOC Director's sole discretion, increasing these committed expenditures during any fiscal year.

3.6.8. Provided further, if the IDOC Defendants fail to spend the amounts allocated under this Agreement pursuant to this Paragraph 3.6 because the amounts allocated exceed the number of inmates with Chronic HCV or exceed the costs required to treat all inmates with Chronic HCV, such failure or failures shall be excused and shall not be a material breach of this Agreement.

3.6.9. IDOC shall disclose to Class Counsel the total amount of money IDOC spent on DAA Treatment, and the total number of inmates who began DAA Treatment, for each fiscal year during the Agreement no later than thirty (30) days after the end of each

respective fiscal year.

3.7. Education for Inmates at Release: Inmates with Chronic HCV who are released from IDOC physical custody and who have not received DAA Treatment shall be provided during the release process with written documentation that (1) informs the inmate of the progression of an HCV infection and potential health complications; (2) informs the inmate where they may be treated in the community and options, if any, for payment mechanism (for example, where Medicaid, Veterans Administration, Medicare or private insurance may be available to pay for that inmate's treatment); (3) recommends that inmates make an appointment with a doctor or clinic in the community to discuss their HCV infection and treatment options; (4) recommends the inmate obtain health insurance and provides information on how to enroll in Idaho Medicaid, if the inmate is not already enrolled in Idaho Medicaid; (5) recommends against unhealthy lifestyles that can increase the progression of HCV; and (6) identifies tips for how inmates can prevent the spread of HCV in the community. Inmates will also be informed that IDOC will provide their medical doctors and clinics in the community with their prison medical file upon execution of a valid written request for release of records.

3.8. Attorney Fees and Costs: In connection with this Agreement, the Parties agree that Class Counsel shall recover fair and reasonable attorney fees as determined by the Court, United States District Court for the District of Idaho, from the common fund to be created by the expenditures required in Paragraphs 3.6.1 through 3.6.5 of this Agreement. The Parties further agree that Class Counsel will recover their reasonable costs as of the date of the Effective Date of the Agreement. The Parties further agree that Corizon, LLC is only responsible to pay (and agrees to pay) $27,421.22 in costs and $100,000.00 in attorney fees, which payment is due and payable within thirty (30) days from the Effective Date of the Agreement.

3.9. Acknowledgement of Consideration: Plaintiffs acknowledge the receipt of good and sufficient consideration from Defendants for the terms and conditions set forth in this Agreement. Plaintiffs expressly release any claim or action upon which they may seek to overturn this Agreement on the grounds of insufficiency of consideration in whole, or in part, as to any Party, regardless of the source of the consideration.

3.10. Process for Final Approval: The Parties recognize that this Agreement shall be subject to Final Approval by the Court pursuant to FRCP 23(e), and hereby agree to the following in order to obtain such Final Approval:

3.10.1. The Parties shall at all times during the Final Approval process cooperate, exercise good faith, and take reasonable efforts necessary to present this Agreement to the Court and obtain the Court's Final Approval.

3.10.2. As soon as practicable following the execution of this Agreement by the Parties, Class Counsel shall take reasonable efforts to obtain Final Approval of this Agreement including, but not limited to, having a class of the Class Members certified for purposes of approving and enforcing this Agreement; having the Court appoint Class Counsel as counsel for the Class Members; having the Court grant an order preliminarily approving this Agreement for the purpose of disseminating notice to Class Members; disseminating notice of this Agreement to the Class Members; and scheduling a Fairness Hearing before the Court.

3.10.3. If the Court does not grant Final Approval of this Agreement as expressly written and intended by the Parties, or if an appeals court reverses the Court's Final Approval, then this Agreement shall be null and void and of no force and effect, and nothing shall be deemed to prejudice the position of any Party with respect to the Action or otherwise, and neither the existence of this Agreement, nor any of its terms or provisions, nor any of the negotiations or proceedings connected with it, shall be admissible in evidence, referred to for any purpose in this Action or in any other litigation or proceeding, or construed as an admission, presumption, or concession by any Party of any liability or for the truth of any of the allegations in this Action.

3.10.4. The Parties do not consent to the Court modifying any final terms of this Agreement subsequent to Final Approval. In the event the Court, after Final Approval, modifies any express term or condition, or enters any order that materially alters the final terms of this Agreement, then at the discretion of either Party, the Agreement shall be rendered null and void; in that event, the Plaintiffs will be entitled to reinstate the Action or may elect to have the Parties return to the mediation process, and then reinstate the Action if mediation is unsuccessful.

3.11. Dismissal of Defendants: Plaintiffs acknowledge that this Agreement shall resolve each and every issue and claim raised by them in this Action against any and all of the IDOC Defendants. Plaintiffs shall dismiss all claims contained in the Operative Complaint in this Action against the IDOC Defendants *with prejudice subject to reinstatement* consistent with the terms of this Agreement. Plaintiffs shall dismiss all claims for injunctive or declaratory relief contained in the Operative Complaint in this Action against the Corizon Defendants *with prejudice subject to reinstatement* consistent with the terms of this Agreement. Plaintiffs shall within fourteen (14) days of the Effective Date of this Agreement file with the Court the attached *Stipulation for Dismissal with Prejudice* and proposed *Order of Dismissal with Prejudice* accomplishing the dismissal of all claims against IDOC Defendants *with prejudice subject to reinstatement* consistent with the terms of this Agreement and the dismissal of the injunctive and declaratory relief claims against the Corizon Defendants *with prejudice subject to reinstatement* consistent with the terms of this Agreement. This Agreement does not apply to Plaintiffs' claims for monetary damages against Corizon Defendants stated in the Operative Complaint and any dismissal of those claims must be set forth in a separate agreement.

3.12. Release of Claims Against Defendants: Subject to the possible reinstatement of this Action pursuant to this Agreement and any enforcement action brought in the Court of Enforcement, Plaintiffs release and forever discharge as follows:

3.12.1. Plaintiffs release and forever discharge IDOC Defendants, the State of Idaho, and each and every former, current, and future officer, director, employee or agent of the State of Idaho and IDOC, from any and all past and present causes of action, liabilities and claims for equitable, declaratory and injunctive relief, including associated expenses, costs and attorney fees, (excluding any claims for damages and any claims for costs and attorney fees arising from any damages claim) whether arising under federal or state law related to the diagnosis, testing, evaluation, management, monitoring, education, or treatment of inmates with HCV, including, but not limited to, treatment with DAA Medications, whether such claims are now known or come to be known in the future.

3.12.2. Plaintiffs release and forever discharge the Corizon Defendants and each and every former or current officer, director, employee, or agent of the Corizon Defendants, from any and all past and present

claims, causes of action, liabilities, expenses, costs, attorney fees, and declaratory relief, injunctive relief, and costs (*excluding any claims for damages and any claims for attorney fees and expenses arising from any damages claim*) whether arising under federal or state law related to the diagnosis, testing, evaluation, management, monitoring, education, and treatment of inmates with HCV, including, but not limited to, treatment with DAA Medications, whether such claims are now known or come to be known in the future.

3.12.3. Plaintiffs release and forever discharge the IDOC Defendants, the State of Idaho, and each and every former, current, and future officer, director, employee or agent of the State of Idaho and IDOC, the Corizon Defendants and each and every former, current, and future officer, director, employee, or agent of the Corizon Defendants, and any future Contractor, and each and every future officer, director, employee or agent of the Contractor from any and all future claims, causes of action, liabilities, expenses, costs, attorney fees, and damages, including claims for monetary damages, declaratory relief, injunctive relief, and costs whether arising under federal or state law, which are based upon or arise from action and conduct required by and undertaken in compliance with the obligations set forth in this Agreement, and which may arise out of conduct, circumstances and/or events which occur after the Effective Date of this Agreement but prior to July 1, 2028, related to the diagnosis, testing, evaluation, management, monitoring, education, or treatment of inmates with HCV, including treatment with DAA Medications, whether such claims are now known or come to be known in the future. The release provided in this subparagraph 3.12.3 prevents the filing of suits alleging the Defendants are complying with the Agreement but should be required to do something different from, in addition to, or beyond the Agreement. Claims which are based upon or arise from action and conduct required by and undertaken in compliance with the obligations set forth in this Agreement are being released pursuant to this Agreement. All claims being released here are therefore "incidental" to the requested injunctive relief. Also, specifically excluded from operation of the release provided in this paragraph are any and all claims for monetary damages against the IDOC Defendants and the Corizon Defendants that have been made

or that could have been made which arise out of conduct, circumstances and/or events which occurred prior to the effective date of this Agreement, and which are related to the diagnosis, testing, evaluation, management, monitoring, education, or treatment of inmates with HCV, including treatment with DAA Medications, whether such claims are now known or come to be known in the future. Also specifically excluded are any and all claims for monetary damages against the IDOC Defendants and the Corizon Defendants or any future Contractor that allege a failure to adhere to the duties and obligations set forth in this Agreement.

3.12.4. This release shall be binding on all Plaintiffs and their agents, representatives, heirs, beneficiaries, assigns, and subrogees.

3.13. Performance Subject to Approvals and Legislative Appropriations: The Parties acknowledge and agree that the IDOC Defendants' performance under this Agreement is specifically pre-conditioned upon and subject to the following:

3.13.1. *Division of Purchasing Approval.* The IDOC Defendants' responsibilities under this Agreement are pre-conditioned upon and subject to IDOC's procurement of medical services required by this Agreement, pursuant to the Idaho Procurement Act, title 67, chapter 92, Idaho Code (the "Act"). IDOC's performance under this Agreement is subject to and conditioned upon receipt of any and all approvals that may be required from the State of Idaho's Department of Administration, Division of Purchasing ("DOP").

3.13.2. *Legislative Appropriations.* The Parties understand and acknowledge that all medical services required by this Agreement shall be paid by the State of Idaho only from appropriations of funding made by the State of Idaho Legislature ("Idaho Legislature"), and that the Idaho Legislature is under no legal obligation to make appropriations and has not yet made any appropriations for purposes of this Agreement. The IDOC Defendants' responsibilities under this Agreement are pre-conditioned upon, and subject to, appropriations by the Idaho Legislature for the payment of medical services set forth in this Agreement. The IDOC Director shall submit a budget request for funding by the Idaho Legislature necessary to begin implementing the terms of this Agreement in FY2021.

3.14. Termination of Agreement Upon Failure of Approvals and Appropriations:

3.14.1. In the event that IDOC Defendants cannot perform the terms of this Agreement contained in paragraph 3.6 and its subparts due to the failure to obtain the necessary approvals and appropriations, or in the event the Idaho Legislature requires a return or give-back of funds, or if the Governor of the State of Idaho mandates reversions, cuts or holdbacks in spending, or if funds are not otherwise budgeted or available to comply with the terms and conditions of this Agreement, or if there is an emergency event beyond the Defendants' control including, but not limited to, acts of God, war, civil disturbances, natural disasters, epidemics, pandemics, or emergency declarations by the local, state, or national government, the termination of the Agreement shall take effect immediately upon the IDOC Director providing written notice to Class Counsel of the termination of this Agreement.

3.14.2. The IDOC Director shall notify Class Counsel in writing at least sixty (60) days prior to the beginning of FY2022, FY2023, FY2024, and FY2025 if the IDOC Defendants are informed that IDOC will be unable to secure the necessary approvals and appropriations to comply with the terms and conditions of this Agreement contained in paragraph 3.6 and its subparts for such next fiscal year. Upon receipt of such notice, Plaintiffs, by and through Class Counsel, shall have the option to terminate this Agreement, which shall take effect thirty (30) days after Class Counsel provides written notice to IDOC Counsel that Plaintiffs have chosen to terminate this Agreement or, if Class Counsel decides at their discretion to return to the mediation process, then thirty (30) days after Class Counsel determines that subsequent mediation efforts are unsuccessful.

3.14.3. In the event this Agreement is terminated as contemplated in this paragraph and its subparts, then all rights and liabilities of the Parties under this Agreement shall cease and neither the IDOC Defendants, IDOC, nor the State of Idaho shall be liable for any penalty, expense, or liability, or for general, special, incidental, consequential or other damages resulting therefrom.

3.14.4. Only upon termination of the Agreement as set forth in this paragraph 3.14 and its subparts may Plaintiffs by and through Class Counsel reinstate this Action in the Court.

3.15. No Admission of Liability: It is expressly understood and agreed that this Agreement is in full and final settlement of the disputed claims for equitable, injunctive and declaratory relief stated in the Operative Complaint, and that any injuries, violations, or damages and the legal liability therefore are disputed and denied, and that this Agreement is based solely on the economic consideration of conservation of public money, and is not to be construed in any way as an admission by Defendants of any liability or wrongdoing whatsoever. Defendants specifically disclaim any liability, violation, injury, damage, or wrongdoing whatsoever on the part of themselves, the State of Idaho, IDOC, or any former or current officer, director, agent, or employee of the State or IDOC. Meanwhile, Plaintiffs continue to maintain that the Defendants in this Action provided unconstitutional and inadequate treatment of inmates with Chronic HCV. Further, nothing in this Agreement may be construed as an admission or finding that the consideration provided in this Agreement is necessary to correct the violation of a federal right. The Parties expressly agree that no Party is a prevailing Party in this Action with regard to an award of attorney fees or for any other purpose. The Court shall not retain jurisdiction over the enforcement of this Agreement and shall not make any findings pursuant to 18 U.S.C. § 3626(a).

3.16. No Basis for Precedent: This Agreement shall not be relied upon as precedent in any future claim or legal proceeding in which the State of Idaho, Defendants, IDOC, and/or any IDOC officer, employee, or agent is named as a party.

3.17. Integration: This Agreement constitutes the entire and exclusive agreement between the Parties and supersedes any and all prior agreements, commitments, oral or written exchanges, offers/counteroffers, and negotiations. There are no promises, representations, agreements, conditions, or understandings that are not fully expressed and incorporated herein. The terms and conditions of this Agreement are contractual and not a mere recital. Further, nothing in this Agreement shall be construed as a consent decree.

3.18. Governing Law: This Agreement shall be deemed to be made and entered into in the State of Idaho and shall in all respects be interpreted, enforced, and governed under the laws of the State of Idaho.

3.19. Severability: Should any provision, term, or condition of this Agreement be declared or be determined by the Court of Enforcement to be illegal or invalid, the validity of the remaining parts, terms, or provisions shall not be affected thereby and said illegal or invalid part, term, or provision shall be deemed not to be a part of this Agreement.

3.20. Modifications: This Agreement may not be amended, modified, altered, changed, rescinded, or supplemented in any manner except by agreement in writing signed by the attorneys for the Parties and approved by the Court.

3.21. Enforcement Upon Material Breach: Unless otherwise provided for in this Agreement, the Parties agree to the following for purposes of providing notice and enforcement of an alleged material breach of this Agreement by Defendants:

3.21.1. Nothing contained in this Agreement is intended or shall be construed as evidence of any intention to confer any rights or remedies upon any person other than the Parties hereto.

3.21.2. The Parties agree that any minor or incidental breach or delay in implementation of a term or condition of this Agreement shall not constitute a material breach.

3.21.3. Upon an alleged material breach of this Agreement by Defendants, Plaintiffs, through Class Counsel only, shall provide IDOC Counsel, in writing, the specific reasons and grounds for such belief, including an identification of the specific provision of which the Defendants are alleged to be in material breach.

3.21.4. IDOC Defendants shall then have thirty (30) days from receipt of the written notice to respond to Class Counsels' written statement. During the thirty- (30) day period, neither Plaintiffs nor Class Counsel shall take any action to enforce the Agreement.

3.21.5. If the alleged material breach is not resolved by or in connection with IDOC Defendants' response, or no response is provided within the thirty- (30) day period for such a response, then Plaintiffs, through Class Counsel only, may file an action in the Court of Enforcement, which the Parties agree shall be the only court with jurisdiction to enforce the Agreement.

3.21.6. If the Court of Enforcement determines that there has been material breach by Defendants of a term or condition of this Agreement, the Court of Enforcement may enter an order consistent with its equitable powers to achieve material compliance of such term or condition. The Court of Enforcement shall not be empowered to award monetary damages as result of a breach of any term or condition of this Agreement.

3.21.7. In any action brought in the Court of Enforcement, the presiding judge may award reasonable attorney fees to the prevailing party or parties only when the judge finds that the non-prevailing party or parties brought, pursued, or defended the action frivolously, unreasonably, or without foundation.

3.21.8. At no point following Final Approval, including during any proceeding to enforce a material breach, may the Parties and/or the Court of Enforcement invite, permit, or otherwise inquire of the Court as to any matter of enforcement or interpretation of this Agreement.

3.21.9. Remedies for any failure of approvals or appropriations shall be governed by paragraph 3.14 of this Agreement rather than this paragraph, 3.21, and its subparts. No alleged or determined material breach may cause or permit a termination of this Agreement or reinstatement of the Action.

3.22. Term and Expiration of Agreement: The terms and conditions of this Agreement shall expire on June 30, 2028. Plaintiffs shall only be entitled to the benefits of this Agreement for the duration of the Agreement.

3.23. Headings and Caption: The headings in this Agreement are for the convenience of the Parties and Court and shall not be used in construing or interpreting this Agreement. Additionally, inclusion of the caption used in the Action is for convenience of the Parties and Court only and shall not be construed as an intention that the Agreement is to be a consent decree, consent judgment, or other agreement whereby the Court retains jurisdiction to interpret, modify, or enforce the Agreement.

3.24. Execution in Counterparts: This Agreement may be executed in counterparts, or with signatures obtained via facsimile or electronic mail

transmission, each of which shall have full force and effect upon execution by all Parties to this Agreement, but which together shall constitute a single instrument.

3.25. Acknowledgements: This Agreement is the result of an arm's-length negotiation. Each Party represents and acknowledges that each Party is, and has been, represented by its own counsel. Each Party further represents and acknowledges that, in executing this Agreement, no Party relies or has relied upon any representations or statements made by any other Party or its counsel other than the promises and representations set forth in this Agreement. Since all Parties contributed substantially, materially, and cooperatively in drafting this Agreement, it shall not be more strictly construed against one Party than any other.

Date: _____

_____
Josh Tewalt
On behalf of IDOC Defendants

Date: _____

_____
Richard Hearn
On behalf of Plaintiffs

Date: _____

_____
John Ingelstrom
On behalf of Plaintiffs

Date: _____

_____
Isaac Lefkowitz, Director
Corizon, LLC
On behalf of Corizon, LLC

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Date: 12/01/2022

Josh Tewalt
On behalf of IDOC Defendants

Date: 12.1.22

Richard Hearn
On behalf of Plaintiffs

Date: 12-1-22

John Ingelstrom
On behalf of Plaintiffs

Date: _____

Isaac Lefkowitz
Corizon, LLC Senior Vice President
On behalf of Corizon, LLC

HEPATITIS C

General Information

What is hepatitis?

"Hepatitis" means inflammation of the liver. The liver is a vital organ that processes nutrients, filters the blood, and fights infections. When the liver is inflamed or damaged, its function can be affected.

Heavy alcohol use, toxins, some medications, and certain medical conditions can cause hepatitis. However, hepatitis is most often caused by a virus. In the United States, the most common types of viral hepatitis are Hepatitis A, Hepatitis B, and Hepatitis C.

Most people who get infected with the Hepatitis C virus develop a chronic, or lifelong, infection.

What is Hepatitis C?

Hepatitis C is an infection of the liver that results from the Hepatitis C virus. **Acute** Hepatitis C refers to the first several months after someone is infected. Acute infection can range in severity from a very mild illness with few or no symptoms to a serious condition requiring hospitalization. For reasons that are not known, about 20% of people are able to clear, or get rid of, the virus without treatment in the first 6 months.

Unfortunately, most people who get infected are not able to clear the Hepatitis C virus and develop a chronic, or lifelong, infection. Over time, **chronic** Hepatitis C can cause serious health problems including liver disease, liver failure, and even liver cancer.

How is Hepatitis C spread?

Hepatitis C is usually spread when blood from a person infected with the Hepatitis C virus enters the body of someone who is not infected. Today, most people become infected with Hepatitis C by sharing needles, syringes, or any other equipment to inject drugs. Before widespread screening of the blood supply in 1992, Hepatitis C was also spread through blood transfusions and organ transplants. While uncommon, poor infection control has resulted in outbreaks in healthcare settings.

While rare, sexual transmission of Hepatitis C is possible. Having a sexually transmitted disease or HIV, sex with multiple partners, or rough sex appears to increase a person's risk for Hepatitis C. Hepatitis C can also be spread when getting tattoos and body piercings in unlicensed facilities, informal settings, or with non-sterile instruments. Also, approximately 6% of infants born to infected mothers will get Hepatitis C. Still, some people don't know how or when they got infected.

What are the symptoms of Hepatitis C?

Many people with Hepatitis C do not have symptoms and do not know they are infected. If symptoms occur, they can include: fever, feeling tired, not wanting to eat, upset stomach, throwing up, dark urine, grey-colored stool, joint pain, and yellow skin and eyes.

When do symptoms occur?

If symptoms occur with acute infection, they can appear anytime from 2 weeks to 6 months after infection. If symptoms occur with chronic Hepatitis C, they can take decades to develop. When symptoms appear with chronic Hepatitis C, they often are a sign of advanced liver disease.

Continued on next page

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

How would you know if you have Hepatitis C?

The only way to know if you have Hepatitis C is to get tested. Doctors use a blood test, called a Hepatitis C Antibody Test, which looks for antibodies to the Hepatitis C virus. Antibodies are chemicals released into the bloodstream when someone gets infected. Antibodies remain in the bloodstream, even if the person clears the virus.

A positive or reactive Hepatitis C Antibody Test means that a person has been infected with the Hepatitis C virus at some point in time. However, a positive antibody test **does not** necessarily mean a person still has Hepatitis C. An additional test called a RNA test is needed to determine if a person is currently infected with Hepatitis C.

Who should get tested for Hepatitis C?

Testing for Hepatitis C is recommended for certain groups, including people who:

- Were born from 1945 – 1965
- Received donated blood or organs before 1992
- Have ever injected drugs, even if it was just once or many years ago
- Have certain medical conditions, such as chronic liver disease and HIV or AIDS
- Have abnormal liver tests or liver disease
- Have been exposed to blood from a person who has Hepatitis C
- Are on hemodialysis
- Are born to a mother with Hepatitis C

Can Hepatitis C be treated?

Yes. However, treatment depends on many different factors, so it is important to see a doctor experienced in treating Hepatitis C. New and improved treatments are available that can cure Hepatitis C for many people.

Testing is the only way to know if you have Hepatitis C.

How can Hepatitis C be prevented?

Although there is currently no vaccine to prevent Hepatitis C, there are ways to reduce the risk of becoming infected with the Hepatitis C virus.

- Avoid sharing or reusing needles, syringes or any other equipment to prepare and inject drugs, steroids, hormones, or other substances.
- Do not use personal items that may have come into contact with an infected person's blood, even in amounts too small to see, such as razors, nail clippers, toothbrushes, or glucose monitors.
- Do not get tattoos or body piercings from an unlicensed facility or in an informal setting.

For more information

Talk to your health professional, call your health department, or visit www.cdc.gov/hepatitis.

EVALUATION AND MANAGEMENT OF HEPATITIS C VIRUS (HCV) INFECTION

Federal Bureau of Prisons

Clinical Guidance

March 2021
(Corrected Version)

WHAT'S NEW IN BOP GUIDANCE FOR HCV INFECTION

This version of the guidance contains the following **major revisions**, based on the January 2021 guidance from the American Association for the Study of Liver Diseases (AASLD):

- **A simplified approach to evaluation and treatment of HCV** is recommended for patients with no past treatment, or current or past history, of decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, HBV or HIV coinfection, or significant drug-drug interactions.

  ➔ See *Sections 1 and 3*

- HCV genotype testing is no longer recommended or required in patients eligible for the simplified approach. This is now used only in determining appropriate treatment regimens for patients with prior treatment failure, relapse, or the conditions listed above.

  ➔ See Laboratory Tests under *Baseline Evaluation*

- Recommended treatment regimens

  ➔ See *Section 6, Recommended Treatment Regimens*

- Only **five** co-formulated direct-acting antiviral (DAA) regimens are now recommended:
  - Elbasvir/grazoprevir (Zepatier®)
  - Glecaprevir/pibrentasvir (Mavyret®)
  - Ledipasvir/sofosbuvir (Harvoni®)
  - Sofosbuvir/velpatasvir (Epclusa®)
  - Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)
- Regimens **no longer** recommended:
  - Paritaprevir/ritonavir/ombitasvir with or without dasabuvir
  - Daclatasvir+sofobuvir
  - Simeprevir
  - Interferon is no longer recommended for **any** regimen.
- **Treatment of acute HCV infection is now recommended**, rather than monitoring for 6 -12 months and observing for spontaneous resolution.
- **Quantitative HCV RNA viral load is recommended** pre-treatment and 12 weeks after the completion of treatment. It is **not** recommended at 4 weeks or at the completion of treatment.

TABLE OF CONTENTS

1. PURPOSE AND OVERVIEW

The Federal Bureau of Prisons (BOP) Clinical Guidance on the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection provides the most current BOP recommendations for the treatment of HCV infection in the federal inmate population.

The current HCV guidance from the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) states that the goal of treatment for HCV-infected persons is to:

- ✓ Reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.

The AASLD/IDSA HCV guidance is updated as new data become available. BOP Health Services Division clinical staff will continue to monitor this guidance and provide updates as necessary. Institution clinical staff are encouraged to review the most recent recommendations by AASLD/IDSA as well as BOP Clinical Guidance to ensure treatment decisions are based on the most current available data.

- Consult the **BOP Health Management Resources** website to determine the date of the most recent update to this document: *http://www.bop.gov/resources/health_care_mngmt.jsp*.
- The **AASLD/IDSA guidance** is available at *https://www.hcvguidelines.org*. See the *References* section in this document for a complete citation.

➢ Simplified Treatment Approach

The AASLD/IDSA HCV guidance **recommends a simplified approach for treatment-naïve patients** with no cirrhosis or with compensated cirrhosis. The BOP HCV guidance has adapted this into three basic steps – **test, evaluate, treat**.

- With the availability of pangenotypic regimens (i.e. a medication regimen that is effective for all HCV genotypes), a simplified approach takes many of the medication selection factors into consideration to get to a treatment decision quickly in certain treatment-naïve patients.
- In such cases, the pre-treatment assessment can be included as part of Step 2 and a simplified regimen may be selected in Step 3 for eligible patients. (*https://www.hcvguidelines.org/treatment-naive/simplified-treatment*; also *https://www.hcvguidelines.org/treatment-naive/simplified-treatment-compensated-cirrhosis*).
- After completing the evaluation summarized below, treatment-naïve inmates with HCV infection may be approved for treatment with an 8-week course of glecaprevir/pibrentasvir if there are no drug-drug interactions, and the patient does not have any of the following conditions: decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, end-stage renal disease with compensated cirrhosis, or coinfection with HBV and/or HIV.

➢ Test, Evaluate, Treat

STEP 1. Test for HCV infection with HCV Ab test.

➔ *Section 2, Screening for HCV Infection*

- Diagnostic evaluation of other conditions
- All inmates screened at least once
- Prenatal testing for each pregnancy
- Periodic risk-based testing related to potential HCV exposure
- On inmate request

STEP 2. Evaluate inmates who are HCV Ab positive.

➔ *Section 3, Evaluation of HCV Ab Positive Inmates.*

- Problem-focused history and physical exam
- **Lab tests**—CBC, PT/INR, liver panel, serum creatinine and eGFR, hepatitis B serology (HBsAg, anti-HBs, anti-HBc total), HIV serology, quantitative HCV RNA viral load.
  - HCV genotype testing is not routinely required in treatment-naïve cases with no decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, chronic hepatitis B virus infection (HBV), or HIV infection.
- **Assess for hepatic cirrhosis/compensation**—Calculate APRI score if no obvious cirrhosis; Calculate Child-Turcotte-Pugh (CTP) score if cirrhosis is known or suspected.
  ➔ *Section 4*, Assess for Hepatic Cirrhosis and Decompensation
- If HCV RNA is detectable, determine eligibility for treatment.
- **Provide patient education** and preventive health care for patients with HCV infection and with cirrhosis.

STEP 3. Treat eligible patients with an approved direct-acting antiviral (DAA) regimen.

- Pre-treatment interventions
  - Obtain a pregnancy test prior to starting treatment.
  - Repeat CBC, PT/INR, liver panel, serum creatinine and eGFR if previous results were obtained more than 6 months ago.
    ➔ *Appendix 4*
- Determine the most appropriate DAA regimen, including an assessment for drug-drug interactions:
  - With the availability of pangenotypic regimens, a simplified approach takes many of the medication selection factors into consideration to get to a treatment decision quickly in certain patients.
  - Following the AASLD/IDSA simplified algorithm, treatment-naïve inmates with HCV infection may be approved for treatment with an 8-week course of glecaprevir/pibrentasvir if there are no drug-drug interactions, and the patient does not have any of the following conditions – decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, end-stage renal disease with compensated cirrhosis, or co-infection with HBV and/or HIV.

- **Refer to** AASLD HCV guidance, DHHS antiretroviral guidelines, University of Liverpool HEP Drug Interactions, and manufacturers' prescribing information for specific drug interactions
  ➔ *References*

- **Submit Nonformulary Request** (NFR) for hepatitis C Treatment Algorithm Request; if approved, submit NFR(s) for specific DAA medication(s)
  ➔ *Appendix 8*
- **Start treatment and follow monitoring schedule**
  ➔ *Section 4* and *Appendix 3*

2. SCREENING FOR HCV INFECTION

➢ Inmate history and patient education

A health history should be obtained from all newly incarcerated BOP inmates. In addition, these inmates should be provided with educational information regarding prevention and transmission, risk factors, testing, and medical management of HCV infection, in accordance with BOP policy. Health education efforts may include use of the BOP peer-oriented video on infectious diseases, ***Staying Alive***,which may be found on the HSD Infection Control Sallyport webpage. Using the page resource link for A-Z Topics, search under "A" for Admission and Orientation (A&O) Videos.

➢ Testing Criteria and Method

Testing for HCV infection is recommended:

- as a screening test for all inmates,
- as part of a diagnostic evaluation of inmates with certain clinical conditions (e.g., elevated liver enzymes of uncertain etiology), and
- prenatal testing for each pregnancy
- periodic risk-based testing related to potential HCV exposure
- for all inmates who request testing.

The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as **HCV Ab (**"anti-HCV" in the AASLD Guidance). The presence of these antibodies only indicates a history of exposure to the HCV virus, but does not distinguish between active and resolved infection.

Initial testing with an **HCV RNA** test is recommended for cases with a known prior positive HCV Ab if they are at risk for reinfection or suspected of reinfection, and if they previously cleared the HCV spontaneously or achieved a sustained virologic response (SVR) with treatment.

An "opt-out" strategy of voluntary testing for HCV infection is recommended for all inmates, regardless of sentencing status, including new intakes and those already in population who have not been previously tested.

An "opt-out" approach involves an informed refusal of testing, rather than informed consent (or "opt in") for testing. After informing a patient of the indications and plan for testing, the particular test is ordered and performed—unless the patient declines it. Testing is considered voluntary and is good clinical practice, but is not required by policy or law. Testing is recommended as soon as practical upon entry into the BOP as well as for inmates already in population who have not been tested previously.

➢ Risk Factors for HCV Infection

The AASLD, CDC, and USPSTF recommend risk factor-based and birth cohort screening for HCV infection. The incarcerated population is reported to have higher prevalence rates of HCV than the general population and is identified by the AASLD and USPSTF as a risk factor for which screening is recommended.

Other well-described risk factors, either for acquiring a new infection or already having HCV infection, which should be considered when recommending HCV testing to inmates, include:

- Has ever injected illegal drugs or shared equipment, including intranasal use of illicit drugs
- Received tattoos or body piercings while in jail or prison, or from any unregulated source
- High-risk sexual activity, especially HIV-infected men who have sex with men
- HIV or chronic hepatitis B virus (HBV) infection
- Received a blood transfusion or an organ transplant before 1992, received clotting factor transfusion prior to 1987, or received blood from a donor who later tested positive for HCV infection
- History of percutaneous exposure to blood (See *BOP Clinical Guidance on Medical Management of Exposures*)
- Has ever received hemodialysis [Order alanine aminotransferase (ALT) monthly and HCV Ab semiannually for inmates on chronic hemodialysis]
- Born to a mother who had HCV infection at the time of delivery
- Born between 1945 and 1965
- Current pregnancy

➢ Clinical Conditions for Testing

HCV testing is recommended for all inmates with the following clinical conditions:

- A reported history of HCV infection without prior medical records to confirm the diagnosis
- Cirrhosis
- Elevated liver enzyme alanine aminotransferase test (ALT) levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis.

➢ Refusal of Testing

Inmates who decline testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits. A **treatment refusal form** is recommended for every testing and treatment refusal.

3. EVALUATION OF INMATES TESTING POSITIVE FOR HCV Ab

Initial evaluation of HCV Ab positive inmates includes: (a) a baseline history and physical examination and (b) baseline lab tests. The inmate should also (c) be assessed regarding the need for preventive health interventions such as vaccines and screenings for other conditions, as well as (d) counseled with information on HCV infection.

Ideally, this evaluation is performed in a timely manner after a positive HCV Ab test result is reported and combines the baseline/initial evaluation and the pre-treatment evaluation into one step.

- A **simplified approach** is recommended, especially for HCV treatment-naïve cases. These cases may then proceed directly to treatment with **an 8-week course of glecaprevir/pibrentasvir** if there are no drug-drug interactions, and the patient does not have decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, or HBV and/or HIV coinfection.
- If **cirrhosis** is present, see *Section 4, Assess for Hepatic Cirrhosis and Decompensation*, to determine whether the liver disease is compensated or decompensated.

➢ Baseline Evaluation

A baseline clinician evaluation should be conducted for all inmates who are HCV Ab positive. At minimum, this evaluation should include the following elements in the **problem-focused history and physical exam:**

- **Evaluate** for signs and symptoms of liver disease, as well as for evidence of HCV sequelae (e.g. cryoglobulinemia, vasculitis).
- **Obtain** a past medical history to include co-occurring medical / mental health conditions and current medications, as well as other pertinent aspects of the patient's medical history.
- **Quantify** prior alcohol consumption, and determine risk behaviors for acquiring HCV infection (See the section on risk factors under *Screening Criteria* (above). Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped, e.g., the time period in which the inmate engaged in injection drug use.
  - **Referral for evaluation and treatment of substance use disorder** is recommended for inmates with evidence for ongoing high-risk behaviors related to drug and alcohol use, e.g., incident reports and sanctions related to drug use during their incarceration.
- **Inquire** about prior treatment for HCV infection, specific medications used, dosages and duration of treatment and outcomes, if known.

➢ Laboratory Tests

Recommended baseline laboratory tests are listed in *Appendix 3* and include the following:

- Complete blood count (CBC); prothrombin time (PT) with International Normalization Ratio (INR); comprehensive metabolic panel (CMP)
  - CMP includes liver panel (albumin, total and direct bilirubin, serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST), and alkaline phosphatase); serum creatinine and calculated glomerular filtration rate (GFR).
  - Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated, to determine the underlying cause, e.g., low hemoglobin/platelet count or GFR.

- Serology for hepatitis A (anti-HAV total), hepatitis B (HBsAg, anti-HBs, and anti-HBc total), and HIV (anti-HIV).
  - Refer to the relevant BOP Clinical Guidance for management of a positive HBsAg or HIV test. These tests may need to be repeated prior to starting HCV treatment if risk factors for transmission have occurred since their last test.
- Quantitative HCV RNA viral load testing, sensitive to ≤ 25 IU/ml, to determine if the inmate has active HCV infection.
  - Undetectable levels of HCV RNA indicate **resolved infection or a false positive** HCV Ab test. Such cases **do not** require ongoing follow-up or monitoring in a chronic care clinic.
- **HCV genotype testing is no longer routinely recommended** for HCV treatment-naïve cases because many of them will be eligible for a pangenotypic regimen.
  - A genotype does need to be obtained when considering SOF/VEL in a patient with cirrhosis as well as in situations where a non-pangenotypic regimen may be required, including: prior HCV treatment failures, decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, HBV and/or HIV coinfection, or drug-drug interactions.
- Consider other possible causes of liver disease, especially alcoholism, nonalcoholic steatohepatitis (NASH), iron overload, and autoimmune hepatitis, as clinically indicated. Unless otherwise clinically indicated, testing for other causes of liver disease—e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin—are not routinely ordered in the evaluation of a positive HCV Ab test.
- A urine drug screen is recommended only if ongoing substance use is suspected or if it is otherwise clinically indicated.

➢ Preventive Health Measures

All inmates who are HCV Ab positive should be evaluated to assess the need for the preventive health interventions. Patients with liver disease should receive standard immunizations that are applicable to an otherwise healthy population, including the following:

- **Hepatitis B vaccine**: Indicated for susceptible inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination. (Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.)
- **Hepatitis A vaccine:** Indicated for susceptible inmates with chronic HCV.
- **Influenza vaccine:** Offer to all HCV-infected inmates annually. (Inmates with cirrhosis are high priority for influenza vaccine.)

  Pneumococcal vaccine: Recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) for use in adults with chronic liver disease, including cirrhosis, regardless of age. Evidence for its use in chronic HCV infection without cirrhosis is limited. (Refer to *BOP Clinical Guidance on Immunizations* for specific recommendations).

➢ Patient Education

Inmates diagnosed with chronic HCV infection should be counseled by a health care provider regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting HCV infection to others, both during incarceration and on release.

4. HEPATIC CIRRHOSIS AND DECOMPENSATION

Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement with fibrotic scar tissue. The natural history of HCV is such that 50–80% of HCV infections become chronic.

Progression of chronic HCV infection to fibrosis and cirrhosis may take years in some patients and decades in others—or, in some cases, may not occur at all. Most complications from HCV infection occur in people with cirrhosis.

- Patients with advanced hepatic fibrosis (primarily stage 3) have a 10% per year rate of progressing to cirrhosis (stage 4).
- Those with cirrhosis have a 4% per year rate of developing decompensated cirrhosis, and a 3% per year rate of developing hepatocellular carcinoma.

➢ Assessing for Advanced Fibrosis and Cirrhosis

Assessment is recommended for all inmates with HCV infection in order to select the most appropriate treatment regimen, prioritize inmates for treatment of HCV, and determine the need for additional health care interventions.

Cirrhosis may be diagnosed in several ways:

- **Symptoms and signs** that support the diagnosis of cirrhosis may include: Low albumin or platelets, elevated bilirubin or INR, ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.
- **The AST-Platelet Ratio Index (APRI) is the BOP-preferred method** for non-invasive assessment of hepatic fibrosis and cirrhosis.
  - The APRI score, a calculation based on results from two blood tests—the AST (aspartate aminotransferase) and the platelet count—is a less invasive and less expensive means of assessing fibrosis than a liver biopsy.
  - The formula for calculating the APRI score is:

    [(AST/AST ULN) x 100] / platelet count (10^9/L)

    ➔ A calculator is available at: *http://www.hepatitisc.uw.edu/page/clinical-calculators/apri*
  - **An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis.** At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see *abdominal imaging studies* bullet below in this list).
  - Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.
  - The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4). Using a cutoff of ≥ 0.7, the sensitivity is 77% and specificity is 72% for significant fibrosis.
  - The APRI score may be invalidated in cases of splenectomy. An alternative non-invasive test (e.g., Fibrosure) may be appropriate. If a person is known to have cirrhosis, the APRI is irrelevant and unnecessary.

- **Liver biopsy is not required** unless otherwise clinically indicated or if there is uncertainty about the stage of fibrosis, based on results from non-invasive testing or other clinical indicators. However, the **presence of cirrhosis on a prior liver biopsy** may be used to meet the BOP criteria for HCV treatment.
- Although a combination of direct biomarkers and transient elastography is emerging as an accurate non-invasive assessment of fibrosis, the data is insufficient at this time to establish it as the new standard over validated indirect biomarkers such as the APRI score.
- **Abdominal ultrasound** is routinely performed in cases of known or suspected cirrhosis, and as clinically indicated on a case-by-case basis. **Abdominal imaging studies** such as ultrasound or CT scan may identify findings consistent with or suggestive of the following:
  - **cirrhosis** (nodular contour of the liver)
  - **portal hypertension** (ascites, splenomegaly, varices), or
  - **hepatocellular carcinoma**

➢ Assessing Hepatic Compensation

Assessing hepatic compensation is important for determining the most appropriate HCV treatment regimen to be used. The recommended HCV treatment regimen may differ depending on whether the cirrhosis is compensated or decompensated.

- The **CTP score** is a useful tool to help determine the severity of cirrhosis and in distinguishing between compensated and decompensated liver disease in patients with known or suspected cirrhosis. However, if the CTP score indicates compensated cirrhosis but the overall clinical picture is suggestive of decompensated cirrhosis, it may be more appropriate to choose a DAA regimen for decompensated cirrhosis.
  - ➧ CTP calculators are readily available on the Internet and are not reproduced in this document. See http://www.hepatitisc.uw.edu/page/clinical-calculators/ctp.
- The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in Table 1 on the next page:

TABLE 1. USING CTP SCORES TO ASSESS HEPATIC COMPENSATION

CTP SCORE	CTP CLASS	HEPATIC COMPENSATION
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	

- Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher.
- It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition.
- Inmates with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for Reduction in Sentence/Compassionate Release in accordance with current policy and procedures.

➢ Additional Interventions for Inmates with Cirrhosis

The following recommendations apply to all inmates with cirrhosis, whether they have ongoing or resolved HCV infection.

- **Pneumococcal vaccine:** Offer to all inmates with cirrhosis.
  ➔ *BOP Clinical Guidance on Immunizations*
- **Hepatocellular carcinoma screening:** Liver ultrasound is recommended **every 6 months** for patients with cirrhosis.
- **Esophageal varices screening:** Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis.

Other healthcare interventions recommended for patients with cirrhosis may include:

- Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
- Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
- Optimized diuretic therapy for ascites
- Lactulose and rifaximin therapy for encephalopathy

In general, **NSAIDs should be avoided** in advanced liver disease/cirrhosis, and **metformin** should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of this document. Other resources should be consulted for more specific recommendations related to this condition.

5. TREATMENT CRITERIA AND PRETREATMENT INTERVENTIONS

Sustained virologic response (SVR) rates of 90% or higher can be achieved with DAA medication regimens. Eradication of HCV is associated with a number of improved outcomes, including a reduction in the following: liver inflammation and fibrosis, severity of advanced liver disease and its complications, risk of liver cancer and liver-related mortality, need for liver transplantation, and transmission of HCV infection.

➢ BOP Eligibility Criteria for HCV Treatment

All sentenced inmates with HCV infection (detectable HCV RNA) are eligible for consideration of treatment. The AASLD/IDSA guidance now recommends treatment for acute HCV infection, rather than monitoring for spontaneous resolution over 6–12 months.

Inmates being considered for treatment of HCV infection should:

- Have no contraindications to, or significant drug interactions with, any component of the treatment regimen.
- Not be pregnant, especially for any regimen that would require ribavirin.
  - Pregnant inmates may be considered for treatment on a case-by-case basis using a shared decision-making model taking into account the lack of data on DAA safety during pregnancy and the risk of transmitting HCV to the baby.

- Have sufficient time remaining on their sentence in the BOP to complete a course of treatment.
  - Inmates with a more urgent need for treatment but insufficient time remaining in BOP custody, may be considered for treatment if they will have access to medications and health care providers for continuity of care at the time of release.
  - Long-term, pre-sentence detainees in BOP custody with higher risk for disease progression or disease complications as described below may be considered for treatment if continuity of care can be reasonably assured and there is reliably sufficient time remaining in custody to complete treatment.
- Have a life expectancy greater than 18 months. Consultation with the Regional Medical Director or Central Office Physician is recommended in cases where life expectancy is uncertain.
- Inmates must demonstrate a willingness and an ability to adhere to a rigorous treatment regimen.
- **Inmates with evidence for ongoing behaviors associated with high risk of HCV transmission** (e.g., injection drug use) **are not automatically excluded** from consideration for HCV treatment.
  - Ideally, such decisions are individualized and made in the context of an integrated model of care in which there is assessment and treatment for substance use disorder, or other disorders intersecting with HCV infection.
  - Data indicate adherence may be high and reinfection rates low in some populations with ongoing risk factors. Furthermore, treatment may have the added benefit of preventing transmission from shared equipment such as needles.
  - Consultation with the Regional HCV Clinical Pharmacist, Regional Medical Director, or Central Office Physician is recommended for making treatment decisions about inmates who become reinfected as a result of ongoing high risk behavior.

Certain conditions are at **higher risk for complications or disease** progression and may require more urgent consideration for treatment, as follows:

- Advanced hepatic fibrosis
  - APRI ≥ 2.0, or
  - Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, or
  - Known or suspected cirrhosis
- Liver transplant recipients
- Hepatocellular carcinoma
- Comorbid medical conditions associated with HCV, including:
  - Cryoglobulinemia with renal disease or vasculitis
  - Certain types of lymphomas or hematologic malignancies
  - Porphyria cutanea tarda
- Immunosuppressant medication for a comorbid medical condition
  - Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. Although data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting, such cases will be considered for prioritized treatment of HCV on an individual basis.

- Evidence for progressive fibrosis
  - Stage 2 fibrosis on liver biopsy, if treatment clinically indicated.
- Comorbid medical conditions associated with more rapid progression of fibrosis
  - Coinfection with HBV or HIV
  - Comorbid liver diseases [e.g., autoimmune hepatitis, hemochromatosis, fatty infiltration of the liver, steatohepatitis (fatty liver disease)]
  - Diabetes mellitus
- Chronic kidney disease (CKD) with GFR ≤ 59 mL/min per 1.73 m2
- Birth cohort 1945–1965
- Continuity of care for those already started on treatment, including inmates who are newly incarcerated in the BOP.

➢ Pre-Treatment Assessment and Interventions

A simplified approach combining Steps 2 and 3 (See *Steps*) into a seamless process is recommended for treatment naïve patients without current or prior history of decompensated cirrhosis, hepatocellular carcinoma, liver transplantation, end-stage renal disease (GFR < 30), HIV or HBV coinfection, or pregnancy.

Pretreatment assessment is recommended within 6 months of the projected start of treatment if there is no cirrhosis or within 3 months, if there is compensated cirrhosis.

Many aspects of the pretreatment assessment also are part of the initial evaluation and do not need to be repeated if consideration for treatment is performed within these time frames. This is an efficient way to accomplish the test-evaluate-treat approach and is recommended whenever feasible.

Pretreatment assessment and interventions include the following:

- **Laboratory tests** including CBC, PT/INR, liver panel, serum creatinine, calculated GFR.
  - Labs do not need to be repeated if obtained within 6 months in patients without cirrhosis or within 3 months in patients with compensated cirrhosis.
  - Consider retesting for HBV and HIV, if ongoing risk factors since last test result.
  - A urine drug screen is not required as part of the pretreatment evaluation, and is recommended only if ongoing substance use is suspected or if it is otherwise clinically indicated.
- Assessment for **hepatic cirrhosis and decompensation**
  - **Calculation of the APRI score** using results from the pretreatment labs. (An APRI score is not needed if there is confirmed cirrhosis.)
  - **Calculation of current CTP score** for inmates with known or suspected cirrhosis.
  - An **abdominal US** is recommended within 6 months of starting treatment for patients with cirrhosis.
- **Pregnancy testing and education** covering the potential risks of DAAs during pregnancy prior to initiating treatment in all women with childbearing potential
  - Ribavirin is contraindicated in pregnancy and in both male and female partners attempting to become pregnant.

- Assessment for significant **drug-drug interactions**
  - Resources for assessing drug interactions with DAA regimens include the AASLD HCV guidance, DHHS antiretroviral guidelines, University of Liverpool HEP Drug Interactions and manufacturers' prescribing information for specific drug interactions.

    → References
- Assessment for **current/prior medication adherence**
- Review of incident report history for **high-risk behaviors** (alcohol/drug possession/use; tattooing).
- **For ribavirin-containing regimens:**
  - A pretreatment ECG is recommended for inmates with preexisting coronary heart disease.
  - If anemia is present and has not been previously evaluated, a diagnostic evaluation is recommended prior to starting treatment.
- **Testing for NS5A resistance-associated substitutions (RASs)** is not routinely indicated, but is recommended prior to treatment with the following regimens or situations:
  - Elbasvir/grazoprevir for **HCV genotype 1a and GFR ≥30.** If RASs are present at position 28, 30, 31, or 93, a regimen other than EBR/GZR should be used.
  - Sofosbuvir/velpatasvir for treatment-naïve **HCV genotype 3** with cirrhosis being considered for 12 weeks of treatment. If the Y93H RAS is present, RBV is added to a 12-week regimen of SOF/VEL.
  - Sofosbuvir/velpatasvir for treatment-experienced **HCV genotype 3** and no cirrhosis.
  - NS5A resistance testing may be considered when ledipasvir/sofosbuvir is an option for treatment-experienced **HCV genotype 1a** with no cirrhosis or compensated cirrhosis.
  - NS3/4A resistance testing is no longer routinely recommended.
- **Patient education**—including, but not limited to: how to take the medication, the importance of adherence, monitoring and follow up, and potential medication side effects. When ribavirin is used, specific counseling about the risks and recommendations related to pregnancy should be provided.

6. RECOMMENDED TREATMENT REGIMENS

➢ Direct Acting Antiviral Medications (DAAs)

Recommendations for **DAA treatment** regimens continue to evolve, but still depend on several factors:

- HCV genotype, except for pangenotypic regimens
- Prior HCV treatment history
- Compensated vs. decompensated liver disease
- Co-occurring medical conditions (HBV or HIV coinfection, hepatocellular carcinoma, chronic kidney disease, solid organ transplant)
- Resistance-associated substitutions (certain clinical scenarios)
- Drug-drug interactions

Special considerations: Certain conditions require special consideration when selecting an HCV treatment regimen, including decompensated cirrhosis, hepatocellular carcinoma, chronic kidney disease and compensated cirrhosis, solid organ transplant recipients, HBV or HIV coinfection, HCV infection with multiple genotypes, and pregnancy. These special considerations are addressed in Section 8.

Cost: The cost of DAA regimens can vary widely. When more than one regimen is appropriate for an individual case, the most cost-effective regimen is recommended, taking into consideration all the factors listed above.

Currently, there are **three classes of HCV DAAs:** NS5A replication complex inhibitors (-asvir), NS5B polymerase inhibitors (-buvir), and NS3/4a HCV protease inhibitors (-previr). These antiviral medications for HCV infection act directly on some part of the virus, usually the replication mechanism.

- **DAAs cannot be used as monotherapy**. They must be used in combination with at least one other DAA with or without ribavirin, depending on the clinical scenario.

The most commonly recommended regimens are described briefly on the next three pages. More detailed information about the regimens and the individual medications—including indications and drug interactions—may be found in the AASLD guidance (*https://www.aasld.org/publications/practice-guidelines*), manufacturer's prescribing information, Facts and Comparisons (available in the Bureau of Electronic Medical Records System (BEMR)), University of Liverpool HEP Drug Interactions website (*https://www.hep-druginteractions.org/checker*), and other validated resources.

Elbasvir/Grazoprevir (Zepatier®)

Formulation/Use: Co-formulation of 50 mg of elbasvir (an HCV NS5A inhibitor) and 100 mg of grazoprevir (an HCV NS3 protease inhibitor) is FDA-approved for treatment of **HCV genotypes 1 and 4**.

- In HCV genotype 1a, NS5A resistance testing is recommended prior to treatment, if GFR is ≥30 .If resistance is identified, selection of a different regimen is recommended.
- For treatment-experienced genotype 4 patients, consider using a different AASLD-recommended regimen.

Dosing and duration: The usual dose and duration is one tablet orally once daily, with or without food, for 12 weeks.

- No dosage adjustment is required for decreased renal function or hemodialysis, although the ribavirin dose must be adjusted for GFR < 50.

Contraindication and uses not recommended:

- Elbasvir/grazoprevir is contraindicated in decompensated cirrhosis (CTP score ≥ 7)
- Contraindicated medications include phenytoin, carbamazepine, rifampin, efavirenz, HIV protease inhibitors (atazanavir, darunavir, lopinavir, saquinavir, and tipranavir), and cyclosporine.
- Elbasvir/grazoprevir is not recommended with moderate CYP3A inducers or with strong CYP3A inhibitors.

Warning: Risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV

Glecaprevir/pibrentasvir (Mavyret®)

Formulation/use: A coformulation of 100 mg of glecaprevir and 40 mg of pibrentasvir is FDA-approved for treatment of **HCV genotypes 1, 2, 3, 4, 5, or 6**, without cirrhosis or with compensated cirrhosis (Child-Pugh A). Glecaprevir/pibrentasvir is also indicated for the treatment of adult patients with **HCV genotype 1** infection, previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Dosing and duration: The usual dose is three tablets (total daily dose: glecaprevir 300mg and pibrentasvir 120 mg) taken orally, once daily, with food. The duration of treatment is either 8, 12, or 16 weeks, as noted below:

- Treatment duration of 8 weeks is recommended for all HCV genotypes with no cirrhosis or with compensated cirrhosis if they are treatment-naïve.
- Treatment duration of 8 weeks is also recommended for genotypes 1, 2, 4, 5, or 6 with no cirrhosis if they are treatment-experienced with PEG-IFN + RBV.
- Treatment duration of 12 weeks is recommended for HCV genotype 1 in PEG-IFN + RBV + NS3/4A protease inhibitor treatment-experienced patients who are NS5A treatment-naïve with no cirrhosis or with compensated cirrhosis.
- Treatment duration of 12 weeks is recommended for HCV genotypes 1, 2, 4, 5, or 6 with compensated cirrhosis if they are treatment-experienced with PEG-IFN + RBV +/- sofosbuvir.
- Treatment duration of 16 weeks, with RBV and daily SOF added, is recommended for all genotypes with no cirrhosis or with compensated cirrhosis and prior treatment failure with GLE/PIB or SOF/VEL/VOX.
- No dosage adjustment is required for patients with any degree of renal impairment, end stage renal disease, or dialysis.

Contraindication and uses not recommended:

- Glecaprevir/pibrentasvir is not recommended for use with certain medications and herbs (e.g., carbamazepine, efavirenz, and St. John's wort).
- It is contraindicated in moderate to severe hepatic impairment (Child- Pugh B or C) or with coadministration with atazanavir and rifampin.

Warning: Risk of hepatitis B virus reactivation in patients co-infected with HCV and HBV.

Ledipasvir/sofosbuvir (Harvoni®)

Formulation/Use: A co-formulation of 90 mg of ledipasvir and 400 mg of sofosbuvir is FDA-approved for treatment of **HCV genotypes 1, 4, 5, and 6**; alone or in combination with ribavirin, without or with cirrhosis, compensated or decompensated.

Dosing and Duration: The usual dose is one tablet orally once daily, with or without food, for 12 weeks.

- AASLD recommends only an 8-week course of treatment in a subgroup of HCV-infected persons who have genotype 1a or 1b, have an HCV viral load < 6 million IU/ml, and are treatment-naïve—but are not HIV-coinfected, and do not have cirrhosis.

- A 24-week course of treatment is recommended for all genotypes with decompensated cirrhosis and either RBV ineligible, or in combination with LD-RBV for prior SOF or NS5A inhibitor based treatment failures.
- No dosage adjustment is required for patients with any degree of renal impairment, end stage renal disease, or dialysis.

Contraindications and Uses not Recommended: Ledipasvir/sofosbuvir is not recommended for use with certain anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital, or oxcarbazepine), certain rifamycin antimycobacterials (e.g., rifabutin, rifampin, or rifapentine), or the antiarrhythmic, amiodarone.

Sofosbuvir/Velpatasvir (Epclusa®)

Formulation/use: A co-formulation of 400 mg of sofosbuvir and 100 mg of velpatasvir is FDA-approved for treatment of **HCV genotypes 1, 2, 3, 4, 5, and 6**, with no cirrhosis or with compensated cirrhosis, or for decompensated cirrhosis in combination with ribavirin.

Dosing and duration: The usual dose is one tablet orally once daily, with or without food, for 12 weeks.

- In genotype 3 with a Y93H RAS, RBV is added to a 12-week regimen for patients who are treatment naïve with compensated cirrhosis or treatment experienced without cirrhosis.
- A 24-week course of treatment is recommended for all genotypes with decompensated cirrhosis and either RBV ineligible, or in combination with RBV for prior SOF or NS5A inhibitor based treatment failures.
- No dosage adjustment is required for patients with severe renal impairment, end stage renal disease, or dialysis.

Contraindications and uses not recommended:

- Sofosbuvir/velpatasvir is not recommended for use with certain anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital, or oxcarbazepine), certain rifamycin antimycobacterials (e.g., rifabutin, rifampin, or rifapentine), the antiarrhythmic amiodarone, certain antiretrovirals (efavirenz, or tipranavir/ritonavir), or proton pump inhibitors.
- If there are contraindicatons to ribavirin, it should not be used in combination with sofosbuvir/velpatasvir.

Warning: The risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV.

Sofpsbuvir/Velpatasvir/Voxilaprevir (Vosevi®)

Formulation/use: A co-formulation of 400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir is FDA-approved for treatment of adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) with **HCV genotypes 1, 2, 3, 4, 5, or 6**, infections previously treated with a

regimen containing an NS5A inhibitor, or **HCV genotypes 1a or 3** infection previously treated with sofosbuvir without an NS5A inhibitor.

Dosing and duration: The usual dose is one tablet (total daily dose: 400 mg of sofosbuvir, 100nmg of velpatasvir, and 100 mg of voxilaprevir) taken orally, once daily, with food, for 12 weeks for all **HCV genotypes** and prior DAA treatment failures with SOF-based regimens, EBR/GZR, or GLE/PIB.

- RBV is added in the following scenarios: 1) compensated cirrhosis, 2) the Y93H RAS is present, or 3) treatment failure with SOF/VEL/VOX or SOF + GLE/PIB.
- A 24-week duration of treatment including RBV is recommended for treatment failures with SOF/VEL/VOX or SOF + GLE/PIB.
- No dosage adjustment is required for patients with severe renal impairment, end stage renal disease, or dialysis.
- SOF/VEL/VOX is primarily recommended for use when treatment has failed with most of the DAA regimens.

Contraindications and uses not recommended:

- Not recommended for use with P-gp inducers and/or moderate to potent CYP inducers (e.g., carbamazepine, St. John's wort). Sofosbuvir/velpatasvir/voxilaprevir is not recommended for use with moderate or severe hepatic impairment (Child-Pugh B or C).
- This drug is contraindicated with co-administration with Rifampin.

Warning: Serious bradycardia may occur with amiodarone coadministration, particularly in patients receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. In patients without alternative viable treatment options, cardiac monitoring is recommended. There is a risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV.

Regimens not recommended

- **Monotherapy** with peginterferon, ribavirin, or any of the DAAs.
- **Dual therapy** with peginterferon and ribavirin.
- **NS3/4 HCV protease inhibitors** (boceprevir, simeprevir, or telaprevir)
- **HCV protease inhibitors for genotypes 2, 3, 5, or 6** (paritaprevir, simeprevir)

➢ Preferred treatment regimen

For eligible treatment-naïve cases, an 8-week course of glecaprevir/pibrentasvir is recommended, regardless of HCV genotype. Cases not eligible for this short-course, pangenotypic regimen, will need to have a genotype test if not previously performed and selection of one of the other AASLD/IDSA-preferred treatment regimens included in the following appendices:

Appendix 1, Treatment Recommendations for Treatment Naïve HCV with No or Compensated Cirrhosis
Appendix 2, Treatment Recommendations for HCV DAA Treatment Failures

➔ Refer to the AASLD/IDSA website (*www.hcvguidelines.org*) for any updates since March 2021.

Alternative treatment regimens: The AASLD/IDSA guidance includes recommendations for some regimens that are not specifically FDA-approved and also describe alternative treatment regimens for

situations in which a preferred regimen is not an option. These alternative regimens are not included in this BOP guidance, but can be considered on a case-by-case basis.

Submit a BEMR non-formulary request for Hepatitis C Treatment Algorithm Request with the necessary supporting documentation (see *Appendix 6*). If approved, submit non-formulary requests for the specific DAA medications.

➢ Potential drug interactions

In addition to the genotype, prior HCV treatment history, and status of hepatic compensation, as noted above, it is essential to review each treatment candidate for potential drug interactions prior to selecting the most appropriate regimen for HCV treatment. Adjustments of the inmate's current medications may be needed prior to starting treatment for HCV. Since information on drug-drug interactions are updated as new information becomes available, medical literature and drug interaction websites should be checked routinely. Useful resources for potential drug interactions include the AASLD/IDSA guidance, the individual manufacturers' prescribing information, University of Liverpool HEP Drug Interactions website, and the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.

7. MONITORING

➔ See *Appendix 3, Hepatitis C Treatment Monitoring Schedule* for a summary chart.

➢ On-treatment monitoring

Outpatient clinic visits are recommended to assess for medication adherence, side effects and symptoms of hepatic decompensation, adverse drug reactions, and drug-drug interactions. Evaluations for routine cases are suggested at 2 weeks and 4 weeks after starting therapy, and monthly thereafter. More frequent evaluations may be needed as clinically indicated, especially for more complex or severe conditions such as HBV or HIV coinfection, decompensated cirrhosis, dialysis or end-stage renal disease, or kidney or liver transplant recipients.

Lab tests are not routinely needed during treatment, except in the following situations:

- **For regimens containing ribavirin:**
  - A CBC should be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly; more frequently as clinically indicated. Ribavirin dosage adjustments may be required.
    ➔ See *Appendix 4, Management of Hematologic Changes*
  - **Pregnancy testing is required** periodically during and after treatment—usually monthly during treatment and for 6 months after completion of treatment when women with childbearing potential are treated **with ribavirin-containing regimens**.
- **For regimens containing elbasvir/grazoprevir**, more frequent monitoring of ALT is necessary:
  - **For 12-week regimens**, a liver panel including ALT should be drawn at 8 weeks, and as clinically indicated. For **16-week regimens**, a liver panel including ALT should be drawn at 8 weeks and again at 12 weeks.
  - **ALT increases of less than tenfold** should be monitored approximately every 2 weeks and consideration given to discontinuation of treatment if the ALT elevations persist. Early discontinuation of HCV treatment is also recommended if ALT increases by tenfold—or if less than tenfold, but accompanied by *symptoms* such as weakness, anorexia, nausea,

vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction.

- **For patients with evidence of chronic HBV infection** (i.e., HBsAg positive) who do not meet established criteria for antiviral HBV therapy, either monitoring of HBV DNA levels or prophylactic HBV antiviral medication may be considered.
  - Monitoring with quantitative HBV DNA levels is done prior to starting HCV DAA treatment, periodically during DAA treatment (usually every four weeks), and immediately after DAA treatment. Initiate antiviral HBV treatment if the HBV DNA level increases more than 10-fold from baseline or above 1,000 IU/ml if it was previously undetectable.
  - Prophylactic HBV antiviral mediation may be initiated prior to or at the same time HCV DAA treatment is started, and continued for 12 weeks after DAA treatment completion.

➢ Post-treatment monitoring

A quantitative HCV RNA viral load assessment is recommended at **12 weeks after completion** of treatment; if HCV is undetectable, it defines a sustained viral response (SVR).

If the HCV viral load is undetectable at 12 weeks after completion of treatment, the inmate may be removed from the chronic care clinic for this condition, if he or she has no cirrhosis, complications, or related comorbidities, and the HCV infection has been changed to "resolved" in the problem list.

Recurrent viremia following an SVR may be due to relapse *or* reinfection. To help distinguish between relapse and reinfection in such cases, an HCV genotype, along with subtyping for genotype 1, should be obtained. If the post-SVR genotype is the same as the pre-treatment genotype, it is not possible to distinguish relapse from reinfection. In addition, ask about and educate on HCV risk factors, assess readiness for retreatment, and consider referring for drug education programming and treatment if there is evidence for ongoing substance use.

➢ Ongoing monitoring

Periodic monitoring is recommended for all those with active infection, including HCV treatment failures, relapse of HCV infection or reinfection, and those with chronic HCV infection who are not yet treated.

- **For cases without advanced fibrosis, cirrhosis, or complications**, annual evaluation is appropriate. This evaluation should include a focused review of systems and patient education relevant to HCV, vital signs and a focused physical examination, and lab monitoring (CBC, PT/INR, liver panel, serum creatinine, calculated GFR, and calculation of the APRI score).

For patients with cirrhosis or significant comorbidities, even in those who achieve SVR after treatment, evaluation is recommended at least every 6 months, and more frequently when clinically indicated.

8. SPECIAL CONSIDERATIONS

➢ HCV Infection with more than one genotype

Very little data are available to guide the selection of a DAA regimen when more than one HCV genotype are present at the same time. In such cases, selection of either a pangenotypic regimen or a regimen that is effective against both of the existing genotypes is appropriate, in consultation with a BOP Hepatitis Clinical Pharmacy Consultant or Central Office Physician.

➢ HBV/HCV Coinfection

In patients coinfected with HBV and HCV, HBV reactivation may occur during or after treatment with HCV DAAs. Testing for HBV infection—including HBsAg, anti-HBs, and anti-HBc total, as well as HBV DNA levels in those with a reactive HBsAg—is recommended for all patients being considered for treatment of HCV infection.

- **If criteria for treatment of HBV are met**, it is recommended that HBV treatment be started prior to or at the same time as HCV treatment, and monitored according to HBV treatment guidance.
- **For patients with evidence of chronic HBV infection (i.e., HBsAg positive) who do not meet established criteria for antiviral HBV therapy**, either monitoring of HBV DNA levels or prophylactic HBV antiviral medication may be considered.
  - **Monitoring with quantitative HBV DNA levels** is done prior to starting HCV DAA treatment, periodically during DAA treatment (usually every four weeks), and immediately after DAA treatment. Initiate antiviral HBV treatment if the HBV DNA level increases more than 10-fold from baseline or above 1,000 IU/ml if it was previously undetectable.
  - **Prophylactic HBV antiviral medication** may be initiated prior to or at the same time HCV DAA treatment is started, and continued for 12 weeks after DAA treatment completion.
- **For isolated anti-HBc total positive cases with negative HBsAg and anti-HBs**, monitor ALT at baseline, at the completion of HCV treatment, and again during post-treatment follow-up.

➢ HIV Coinfection

Currently recommended HCV regimens are equally effective for HCV mono-infection and coinfection with HIV. However, an alternative HCV regimen or an alternative antiretroviral medication regimen may be necessary due to potential drug interactions between the HCV DAAs and certain antiretrovirals.

The following are links to tables showing drug interactions between the HIV antiretrovirals and the HCV Direct Acting Antivirals (DAAs):

➔ See https://aidsinfo.nih.gov/guidelines/htmltables/1/7363

➔ See https://www.hcvguidelines.org/unique-populations/hiv-hcv

➢ Decompensated Cirrhosis

Treatment of HCV patients with decompensated cirrhosis should be managed in consultation with an experienced clinician/specialist, with treatment requests considered on a case-by-case basis. The regimens and other considerations listed below are for those with a current or prior history of decompensated cirrhosis. Inmates with decompensated cirrhosis and a CTP score ≥ 10 (Class C) may meet reduction in sentence criteria.

➔ See **Table 2** on the next page for a summary of treatment recommendations for decompensated cirrhosis.

TABLE 2. HCV TREATMENT RECOMMENDATIONS FOR DECOMPENSATED CIRRHOSIS (CURRENT OR PRIOR HISTORY)

TREATMENT HISTORY	HCV GENOTYPES AND TREATMENT REGIMENS
RBV eligible (except TF with SOF or NS5A regimens; see below)	LDV/SOF + RBV-LD: 12 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL + RBV*: 12 wks (genotypes 1–6)
RBV ineligible	LDV/SOF: 24 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL: 24 wks (genotypes 1–6)
TF with SOF or NS5A regimens (RBV eligible)	LDV/SOF + RBV-LD: 24 wks (genotypes 1, 4, 5, or 6 only) SOF/VEL + RBV*: 24 wks (genotypes 1–6)

ABBREVIATIONS: See *GLOSSARY*.

* A full weight-based ribavirin dose may be started in cases with CTP Class B decompensated cirrhosis, while low initial dose is used in cases with CTP Class C.

➢ Hepatocellular carcinoma

The presence of HCC may impact both the timing of HCV treatment and the choice of DAA treatment regimen. The timing of treatment for HCV relative to the treatment of HCC is an important consideration that is impacted by the choice of treatment for HCC and the patient's life expectancy, and is recommended to be done in collaboration with the treating oncologist.

- In the context of HCV infection, HCC usually occurs in the presence of cirrhosis. Whether cirrhosis is compensated or decompensated affects the choice of DAA medication.
- The SVR rates are lower for patients with HCC than those who don't have HCC. Therefore, these cases are not eligible for the shorter 8-week treatment regimens. Additional data is needed to determine whether a longer duration of treatment will achieve a higher SVR rate.

➢ Transplant Recipients

Consultation with a transplant specialist is recommended before and in conjunction with treatment of HCV in liver, kidney or other solid organ transplant candidates or recipients. AASLD-recommendeded HCV DAA regimens for liver or kidney transplant recipients, as well as potential DAA drug interactions with anti-rejection medications, may be found at https://www.hcvguidelines.org/unique-populations

➢ Chronic kidney disease (CKD)

HCV is independently associated with the development of chronic kidney disease (CKD). Published studies indicate that HCV is associated with 1) a higher risk of developing proteinuria and CKD; 2) a higher risk for progression to end-stage-liver-disease (ESLD); and 3) an increased risk of mortality for dialysis patients.

- Patients with CKD, HCV and no cirrhosis may be considered for the simplified approach to treatment. Those with cirrhosis are not eligible for the simplified approach.

- **No dosage or duration adjustment is required for any degree of renal impairment when using any of the currently recommended DAAs** including elbasvir/grazoprevir (genotypes 1 or 4), glecaprevir/pibrentasvir (genotypes 1-6), ledipasvir/sofosbuvir (genotypes 1, 4, 5, or 6), or sofosbuvir/velpatasvir (genotypes 1-6).
- **Ribavirin doses must be decreased with GFRs ≤50**. For GFRs 30–50, ribavirin is dosed 200 mg alternating every other day with 400 mg. For GFR < 30, including hemodialysis, the ribavirin dose is 200 mg daily. Consultation with a transplant specialist is recommended prior to and in conjunction with treatment of HCV in kidney transplant candidates or recipients.

➢ Pregnancy Considerations

The current AASLD/IDSA guidance recommends consideration of treatment of HCV during pregnancy or breastfeeding on an individual basis only if the benefits outweigh the potential or unknown risks.

- Testing for HCV infection is recommended as part of prenatal care for each pregnancy.
- Treatment of HCV infection is recommended before becoming pregnant to decrease the risk of maternal-infant transmission.
- **Ribavirin is contraindicated during pregnancy:**
  - **Women with childbearing potential** who are being considered for an HCV regimen that includes ribavirin should be counseled on the adverse fetal effects of ribavirin. They should be advised not to become pregnant during treatment with ribavirin—and for 6 months after the treatment has ended. They should also be advised that the same risks apply if a male sex partner is being treated with ribavirin. A negative pregnancy test should be documented before starting treatment with ribavirin, then monthly during treatment and monthly for 6 months after treatment.
  - **Men being treated with ribavirin** should also be counseled on the adverse fetal effects of ribavirin. They should be advised not to cause pregnancy in their female sex partners during treatment with ribavirin—and for 6 months after the treatment has ended.
- HCV RNA testing is recommended prior to initiating treatment in the postpartum period to determine if spontaneous resolution of HCV infection occurred during the pregnancy.

References

AASLD/IDSA. Recommendations for testing, managing, and treating hepatitis C. *AASLD/IDSA website.* *http://www.hcvguidelines.org*. Updated January 21, 2021. Accessed February 2021. Refer to this website for any updates since November 2019.

Note about the AASLD/IDSA website: To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management.

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. AIDSinfo website. *https://aidsinfo.nih.gov/guidelines*. Updated October 17, 2017. Accessed August 2018.

Glossary of Abbreviations

MEDICATIONS	
DAA	direct acting antiviral medication
DCV	daclatasvir
DSV	dasabuvir
EBR	elbasvir*
GLE	glecaprevir*
GZR	grazoprevir*
LDV	ledipasvir*
OBV	ombitasvir
PTV	paritaprevir
PEG-IFN	pegylated interferon, peginterferon
PI	protease inhibitor
PIB	pibrentasvir*
PrO	paritaprevir/ritonavir/ombitasvir
PrOD	paritaprevir/ritonavir/ombitasvir/dasabuvir
RBV	ribavirin
RBV-LD	ribavirin, low initial dose
SOF	sofosbuvir*
SMV	simeprevir
VEL	velpatasvir*
VOX	voxilaprevir*
* Medications marked with an asterisk (*) are direct acting antiviral medications (DAAs).	
OTHER TERMS	
AASLD	American Association for the Study of Liver Diseases
ALT	alanine aminotransferase
ANA	antinuclear antibody
APRI	AST to Platelet Ratio Index
AST	aspartate aminotransferase
CBC	complete blood count
CTP score	Child-Turcotte-Pugh score
EGD	esophagogastroduodenoscopy
GFR	glomerular filtration rate
HBV	hepatitis B virus
HBsAg	hepatitis B surface antigen
HCC	hepatocellular carcinoma
HCV	hepatitis C virus

HIV Ab or anti-HIV	HIV antibody
IDSA	Infectious Diseases Society of America
INR	International Normalization Ratio
NASH	nonalcoholic steatohepatitis
PT	prothrombin time
RAS	resistance-associated substitution
SVR	sustained virologic response
TE	treatment-experienced
TF	treatment failure
TN	treatment-naïve
ULN	upper limit of normal

Appendix 1. Treatment Recommendations for Treatment Naïve HCV Infection

DAA TREATMENT OPTIONS FOR TREATMENT NAÏVE HCV INFECTION [A, B, C, D] (No Cirrhosis or Compensated Cirrhosis)					
DAA Regimen	**Genotype**				
	1	**2**	**3**	**4**	**5/6**
GLE/PIB 8 wks[E]	✓	✓	✓	✓	✓
SOF/VEL 12 wks[E]	✓	✓	✓	✓	✓
LDV/SOF 12 wks[E]	✓			✓	✓
EBR/GZR 12 wks[E]	✓			✓	

NOTES:

A. All regimens in this Appendix are identified as RECOMMENDED in the AASLD guidance. Alternative regimens may be appropriate in some cases, but are not included in this table. Some AASLD recommended regimens are not FDA-approved, but are based on available evidence.

B Choice of regimen is determined by HCV genotype, treatment history, presence of compensated cirrhosis or no cirrhosis, and resistance-associated substitutions; it is also influenced by potential drug interactions and cost.

C. Recommendations in this table may not be appropriate in decompensated cirrhosis, hepatocellular carcinoma with compensated or decompensated cirrhosis, chronic kidney disease with GFR < 30, liver or kidney transplant recipients, HCV infection with multiple genotypes, HIV infection, or if there are NS5A RASs. Refer to the specific sections in this guidance and the AASLD/IDSA guidance for treatment of HCV in these situations.

D. Simplified approach to treatment: GLE/PIB or SOF/VEL are recommended regimens for patients without the above co-occurring conditions.

E. Exceptions to the standard treatment regimens above:

1) GLE/PIB: in patients with HCV/HIV coinfection and compensated cirrhosis, a 12 week regimen is recommended for all genotypes.

2) SOV/VEL: in treatment naïve genotype 3 with a Y93H RAS and compensated cirrhosis, RBV is added to the regimen.

3) LDV/SOF: 8 weeks may be considered for treatment naïve HCV genotypes 1 or 4 without cirrhosis and VL < 6 million IU/m and no HIV co-infection. Do not use LDV/SOF in subtype 6e, if known.

5) EBR/GZR: in genotype 1 with an NS5A RAS, do not use EBR/GZR.

MEDICATIONS:

EBR/GZR=elbasvir/grazoprevir; ***GLE/PIB*** = glecaprevir/pibrentasvir (Mavyret™); ***LDV/SOF*** = ledipasvir/sofosbuvir (Harvoni ®); ***RAS***=Resistance-Associated Substitutions; ***RBV*** = weight-based ribavirin; ***SOF*** = sofosbuvir; ***SOF/VEL*** = sofosbuvir/velpatasvir (Epclusa®); **SOF/VEL/VOX** = sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

Appendix 2. Treatment Recommendations for DAA HCV Treatment Failures

Specific DAA Regimen that Failed	Treatment Options for DAA Treatment-Experienced HCV [A, B, C, D, E, F]			
	Genotype 1, 2, 4, 5, or 6		Genotype 3	
	No Cirrhosis	Compensated Cirrhosis	No Cirrhosis	Compensated Cirrhosis
GLE/PIB	▸ **GLE/PIB+SOF+RBV:** 16 wks			
	▸ **SOF/VEL/VOX:** 12 wks	▸ **SOF/VEL/VOX+RBV:** 12 wks	**SOF/VEL/VOX:** 12 wks	▸ **SOF/VEL/VOX+RBV:** 12 wks
EBR/GZR *or* SOF-based regimens (SOF + RBV + PEG-IFN *or* SOF + NS5Ai)	▸ **SOF/VEL/VOX:** 12 wks		▸ **SOF/VEL/VOX:** 12 wks	▸ **SOF/VEL/VOX+RBV:** 12 wks
SOF/VEL/VOX or SOF + GLE/PIB	▸ **GLE/PIB+SOF+RBV:** 16 wks[G] ▸ **SOF/VEL/VOX+RBV:** 24 wks			

Notes:

A. All regimens in this Appendix are identified as RECOMMENDED in the AASLD guidance. Alternative regimens may be appropriate in some cases, but are not included in this table. Some AASLD recommended regimens are not FDA-approved, but are based on available evidence.

B Choice of regimen is determined by HCV genotype, treatment history, presence of compensated cirrhosis or no cirrhosis, and resistance-associated substitutions; it is also influenced by potential drug interactions and cost.

C. Recommendations in this table may not be appropriate in decompensated cirrhosis, hepatocellular carcinoma with compenstated or decompensated cirrhosis, chronic kidney disease with GFR < 30, liver or kidney transplant recipients, HCV infection with multiple genotypes, HIV infection, or if there are NS5A RASs. Refer to the specific sections in this guidance and the AASLD/IDSA guidance for treatment of HCV in these situations.

D. Treatment- Experienced w/ PEG-IFN + RBV +/- NS3/4 PI. AASLD/IDSA guidance makes no treatment recommendations for treatment failures with PEG-IFN + RBV+/- NS3/4 PI based on SVR rates of current DAA regimens being similar to those of treatment naïve patients. Consultation with a BOP Regional Hepatitis Clinical Pharmacist is recommended prior to starting treatment. In general, the regimens for treatment naïve HCV infection may be followed for this treatment experienced group. However, the following modifications are recommended in the prescribing information for each specific scenario below.

1) GLE/PIB is recommended for 12 weeks rather than 8 weeks for genotype 1.
2) RBV is added to a 12 week regimen of EBR/GZR for genotypes 1a or 1b..
3) RBV is added to a 16 week regimen of EBR/GZR for genotype 4.
4) For genotypes 1, 4, 5, or 6, LDV/SOF is recommended for 24 weeks or for 12 weeks with added RBV.,

E. Treatment failures with PrO are not specifically addressed by AASLD/IDSA, but this regimen is most like GLE/PIB.

F. Treatment failures with PrOD are not specifically addressed by AASLD/IDSA, but this regimen is most like SOF/VEL/VOX.

G. Consider extending treatment to 24 weeks in genotype 3 with cirrhosis or SOF + GLE/PIB failure.

MEDICATIONS:

GLE/PIB = glecaprevir/pibrentasvir (Mavyret™); ***LDV/SOF*** = ledipasvir/sofosbuvir (Harvoni ®);
PEG-IFN = pegylated interferon (peginterferon); **NS3/4 *PI*** = protease inhibitor (boceprevir, telaprevir, simeprevir);
PrO = paritaprevir/ritonavir/ ombitasvir; ***PrOD*** = paritaprevir/ritonavir/ombitasvir + dasabuvir;
RBV = weight-based ribavirin; ***SOF*** = sofosbuvir; ***SOF/VEL*** = sofosbuvir/velpatasvir (Epclusa®);
SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

Appendix 3. Hepatitis C Treatment Monitoring Schedule

Evaluation[1, 2]	Baseline (HCV Ab positive)	Pretreatment (Within 180 days of Tx)	On-Treatment Monitoring (by week of treatment)							12 wks Post-Tx
			2	4	8	12	16	20	24	
Clinician evaluation	X	X	X	X	X	X	X	X	X	X
HIV Ab, HBV Serology[3], Anti-HAV (IgG)	X									
Prothrombin Time/INR	X	X								
CBC[4]	X	X								
Serum creatinine + eGFR	X	X								
ALT, AST, bilirubin, alkaline, phosphatase, albumin[5]	X	X	*As clinically indicated* [4,5]							
APRI & CTP scores[6]	X	X								
HCV RNA, quantitative [7]	X									X
HCV genotype[2]										
Assess for drug-drug interactions & adherence		X	*At each clinician evaluation during treatment.*							
Review incident report history for high-risk behavior (alcohol/drug possession/use; tattooing)		X	*If indicated.*							
Urine pregnancy test[8] (if childbearing potential)		X		*Monthly while on treatment with RBV*						*monthly x 6 mos*

1 Conduct further diagnostic evaluations as clinically warranted to identify other potential causes of the patient's liver disease such as hemochromatosis, Wilson's disease, or autoimmune hepatitis (e.g., serum iron, serum copper, ANA/ ESR). If any of these conditions are diagnosed or strongly suspected, a pre-treatment liver biopsy should be considered.

2 **Baseline and Pretreatment evaluations may be combined and HCV genotype testing is not routinely recommended as part of a simplified approach** to HCV treatment in treatment-naïve cases with no current or prior history of decompensated cirrhosis, hepatocellular carcinoma, liver or other solid organ transplant, chronic kidney disease with compensated cirrhosis, HBV or HIV infection, pregnancy, or significant drug interactions with glecaprevir/pibrentasvir.

3 **Recommended baseline testing for hepatitis B status includes HBsAg, anti-HBs, and anti-HBc total.** If either HBsAg or anti-HBc total is positive, obtain an HBV DNA viral load. If criteria for treatment of HBV are met, initiating antiviral therapy for HBV is recommended prior to or at the same time as HCV treatment. If criteria for treatment of chronic HBV infection are not met, either monthly HBV DNA viral loads or prophylactic HBV antiviral medication are recommended during treatment for HCV.

4 On-treatment monitoring of CBCs is indicated for RBV-containing regimens at 2 weeks, 4 weeks, then monthly while on treatment, and more frequently as clinically indicated. **RIBAVIRIN-CONTAINING REGIMENS: A pretreatment ECG is recommended for inmates with preexisting coronary heart disease.**

5 **More frequent monitoring of ALT is necessary in certain situations: 1) Regimens containing elbasvir/grazoprevir:** An ALT should be drawn at 4 weeks and again at 8 weeks, and as clinically indicated. For 16-week regimens, an ALT should also be drawn at 12 weeks; **2) Patients with compensated cirrhosis** who are treated with paritaprevir/ritonavir/ ombitasvir, with or without dasabuvir, require more frequent monitoring of ALT; **3) Increases in the ALT should prompt more frequent monitoring or early discontinuation.** Asymptomatic ALT increases of less than tenfold should be monitored approximately every 2 weeks. Early discontinuation of HCV treatment is recommended if ALT increases by tenfold—or if less than tenfold , but accompanied by *symptoms* such as weakness, anorexia, nausea, vomiting, or change in stool color, or *signs* including elevations in conjugated bilirubin, alkaline phosphatase, and INR, related to hepatic dysfunction

6 A CTP score is calculated only for cases with known or suspected cirrhosis.

7 For treatment regimens recommended in this document, the **routine schedule of HCV RNA testing** includes baseline testing and 12 weeks after completion of therapy. If HCV RNA is undetectable12 weeks after treatment, no further follow-up for HCV is required.

8 On- and post-treatment monitoring for pregnancy is recommended only for RBV-containing regimens. A pre-treatment pregnancy test is recommended for all regimens.

Appendix 4. Management of Hematologic Changes

Note: For patients prescribed a direct-acting antiviral (DAA) for HCV infection, if ribavirin must be discontinued due to hematologic changes, the DAA also may need to be discontinued. Consultation with an experienced clinician is recommended.

HEMOGLOBIN (Hgb)

Value	*Ribavirin Adjustment and Supportive Treatment*	
10–11 g/dL	***Ribavirin*** → ► If no or minimal symptoms, then no dose modification. ► If symptomatic, decrease ribavirin by 200 mg/day.	***Candidates for Erythropoietin:*** Rule out other causes of anemia. If anemia persists at 2 weeks after reducing ribavirin—and there is no hypertension—then consider erythropoietin, especially if the patient demonstrates a virologic response. Erythropoietin should be considered primarily for patients who are cirrhotic, post-transplant, HIV/HCV coinfected, or treated with a DAA. ***Dosage:*** Epoetin alfa 40,000 units subcutaneously weekly ***Goal:*** Hemoglobin 12 g/dL ***Note:*** If hemoglobin is <12 g/dL for more than 4 weeks at the reduced/adjusted dose, then discontinue ribavirin.
8.5–10 g/dL	***Ribavirin*** → ↓ to 600 mg daily (200 mg AM & 400 mg PM)	
< 8.5 g/dL	***Ribavirin*** → Discontinue until resolved.	

Appendix 5. Resources—Prevention and Treatment of Viral Hepatitis

HEALTH CARE PROFESSIONALS

American Association for the Study of Liver Diseases and Infectious Disease Society of America Hepatitis C Guidance
http://www.hcvguidelines.org

Centers for Disease Control and Prevention
National Center for Infectious Diseases—Hepatitis Branch
http://www.cdc.gov/ncidod/diseases/hepatitis/

MELD Score Calculator
http://optn.transplant.hrsa.gov/converge/resources/MeldPeldCalculator.asp?index=98

National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
http://www.niddk.nih.gov

National Clinicians' Post-Exposure Prophylaxis PEPline: (888) 448-4911
http://www.nccc.ucsf.edu/

U.S. Department of Veterans Affairs National Hepatitis C Program
http://www.hepatitis.va.gov/

PATIENT EDUCATION

American Liver Foundation (ALF)
http://www.liverfoundation.org

Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/idu/hepatitis/index.htm

Hepatitis Foundation International (HFI)
http://www.hepfi.org

The National Digestive Diseases Information Clearinghouse (NDDIC)
http://www.digestive.niddk.nih.gov/ddiseases/pubs/hepc_ez/index.htm

U.S. Department of Veterans Affairs National Hepatitis C Program—For Veterans and the Public
http://www.hepatitis.va.gov/patient/index.asp

Appendix 6. Hepatitis C Treatment Algorithm/Nonformulary Request Worksheet

The BOP *Hepatitis C Treatment Algorithm/Nonformulary Request Worksheet* is available on the next page.

February 2021 **Hepatitis C Treatment Algorithm/Nonformulary Request Worksheet**

U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

Inmate Name:	**Projected Release Date:**
Register Number:	**Weight (lb.):** (within 90 days of request)
APRI Score: APRI Date: APRI = ([AST/ULN AST]/Plt) x 100	**HCV Genotype:** 1a 1b 2 3 4 5 6
CTP Score (if cirrhotic): Date: **POINTS (circle):** 1 2 3 **Albumin (g/dL):** >3.5 2.8-3.5 <2.8 **Bilirubin (mg/dL):** <2 2-3 >3 **INR:** <1.7 1.7-2.3 >2.3 **Encephalopathy:** none grade 1-2 grade 3-4 **Ascites:** none diuretic responsive diuretic refractory	**Liver Biopsy Result (amount of fibrosis):** Date Performed: ☐ Not Performed ☐ Portal ☐ Periportal ☐ Bridging ☐ Cirrhosis ☐ None **Note:** For regimens with elbasvir/grazoprevir in the treatment of HCV genotype 1a, an HCV NSSA virologic resistance test is required.

Prior Antiviral Treatment for HCV: ☐ No ☐ Yes If yes, answer the following:

Drug Names and Dosages:

Start Date: Stop Date: Reason stopped:

Prior Treatment Response ☐ SVR ☐ Relapser ☐ Partial Responder ☐ Null Responder

Requested Treatment Regimen (check all that apply):

☐ Ledipasvir/sofosbuvir (Harvoni®)
☐ Elbasvir/grazoprevir (Zepatier®)
☐ Glecaprevir/pibrentasvir (Mavyret™)
☐ Sofosbuvir/velpatasvir (Epclusa®)
☐ Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)
☐ Ribavirin ☐ Other_____

Eligibility Criteria:

☐ Sentenced inmate with sufficient time remaining on sentence to complete a course of treatment prior to halfway house (RRC), home confinement, or GCT/Full Term release, and Life Expectancy > 18 mo.

☐ Inmate is willing and able to adhere to a rigorous treatment regimen (no documented non-adherence to prior therapy, failure to complete pretreatment evaluation process, or unwillingness to commit or consent to HCV treatment).

☐ No contraindications or drug interactions with requested treatment regimen

☐ No uncontrolled or unstable medical or mental health conditions.

☐ No current pregnancy

Health Services Staff Name / Signature / Date / Institution

Documentation - include copies of the following with the BEMR non-formulary request:

☐ CBC, serum creatinine and eGFR, liver panel, INR (dated within 180 days of request)

☐ HCV RNA viral load (reported as IU/ml) (anytime prior to treatment)

☐ HCV genotype (anytime prior to treatment)if not treatment naïve or a candidate for simplified treatment.

☐ HIV Ab - if positive, include CD4 and HIV viral load (dated within 180 days of request) and current antiretroviral medication regimen

☐ Hepatitis B serology (sAb, sAg, and cAb)- if HBsAg reactive, include eAg, eAb, and HBV DNA viral load

☐ Liver biopsy report (if performed, but not required unless clinically indicated)

☐ If cirrhosis or APRI ≥ 2 (defined by pathology or clinical findings), include abdominal US or CT

☐ Pregnancy test if woman with child-bearing potential (dated within 90 days of request)

PROCEDURE FOR SUBMITTING HCV TREATMENT REQUEST

- Generate a BEMR non-formulary request (NFR) for Hepatitis C Treatment Algorithm.
- Include all information and attach all required documentation from above.
- May scan and attach Hepatitis C Treatment Algorithm Nonformulary Request Worksheet to NFR.

EXHIBIT C

Master Service List

CreditorName	CreditorNoticeName	Address1	Address2	City	State	Zip	Phone	Fax	Email	Description
Aakash Dalal SBI# 792652E		215 Burlington Road South		Bridgeton	NJ	08302				Interested Party
Alight	Jessica Lazenby	P.O. Box 95135		Chicago	IL	60694-5135			Jessica.lazenby@alight.com	Top 30 Creditor
Anant Kumar Tripati #102681		P.O. Box 8909		Yuma	AZ	85349	928-627-8871			Interested Party
Arizona DOC	Tim Bojanowski	Struck Love Bojanowski & Acedo, PLC	3100 W. Ray Rd, Ste 300	Chandler	AZ	85226			bojanowski@strucklove.com	Top 30 Creditor
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC	Susan C. Mathews	1301 McKinney Street, Suite 3700		Houston	TX	77010	713-286-7165	713-650-9701	smathews@bakerdonelson.com	Counsel for Maxim Healthcare Staffing Services, Inc.
BDO	Randy Wise	P.O. Box 642743		Pittsburgh	PA	15264-274				Top 30 Creditor
Bio-Rad Laboratories, Inc.	Thomas Burg	1000 Alfred Nobel Drive		Hercules	CA	94547			thomas@bbslaw.com	Top 30 Creditor
Blue Cross Blue Shield of MI	Paul Wilk, Jr.	600 East Lafayette Boulevard		Detroit	MI	48226-2996			Paul.wilk@kitch.com	Top 30 Creditor
Brown & Crouppen, P.C.	Stephen L. Bishop	2345 Grand Blvd., Ste. 675		Kansas City	MO	64108	816-350-9158	816-298-6437	stephenb@getbc.com	Counsel for Ginger Headley and Mark Coffelt
Brown Fox PLLC	Eric C. Wood	6303 Cowboys Way, Suite 450		Frisco	TX	75034	214-327-5000	214-327-5001	eric@brownfoxlaw.com	Counsel for Consilium Staffing, LLC
Cameron Regional Medical Center	Mark Cole	1600 East Evergreen		Cameron	MO	64429			mcole@spencerfane.com	Top 30 Creditor
Canon Financial	Brian Fleischer	14904 Collections Drive		Chicago	IL	60693-0149			bfleischer@fleischerlaw.com	Top 30 Creditor
Capital Region Medical Center/Curators of the University of MO	Patrick Stueve, Tom Luebbering	1125 Madison Street		Jefferson City	MO	65101	573-632-5001		stueve@stuevesiegel.com; tluebbering@crmc.org	Top 30 Creditor and Committee of Unsecured Creditors
Capitol Eye et al.	Blake Marcus	1705 Christy Drive, #101		Jefferson City	MO	65101			Blake.m@carsoncoil.com	Top 30 Creditor
Cell Staff	Mike Landon	1715 N Westshore Boulevard		Tampa	FL	33607			mlandon@cellstaff.com	Top 30 Creditor
Christopher D. Harrell WMCI #26939		7076 Road 55F		Torrington	WY	82240-7771				Interested Party
Dell Financial Services, LLC	Richard Villa	P.O. BOX 6547		Carol Stream	IL	60197-6547			collections@slollp.com	Top 30 Creditor
Doshi Legal Group, P.C.	Amish R. Doshi	1979 Marcus Avenue	Suite 210E	Lake Success	NY	11042	516-622-2335		amish@doshilegal.com	Counsel to Mitsubishi HC Capital America, Inc. f/k/a Hitachi Capital America, Corp.
Dowd Bennett LLP	Philip A. Cantwell, Robyn Parkinson	7733 Forsyth Blvd., Suite 1900		St. Louis	MO	63105			pcantwell@dowdbennett.com; rparkinson@dowdbennett.com	Counsel to YesCare Corp. and CHS TX
Duke Evett, PLLC	Keely E. Duke and Molly E. Mitchell	P.O. Box 7387		Boise	ID	83702	208-342-3310	208-342-3299	ked@dukeevett.com; mem@dukeevett.com	Counsel for Saint Alphonsus Health System, Inc
Edward Albert Stenberg #124629	Lakeland Correctional Facility	141 First St.		Coldwater	MI	49036				Interested Party
Fleischer, Fleischer & Suglia, P.C.	Nicola G. Suglia	Four Greentree Centre	601 Route 73 North, Suite 305	Marlton	NJ	08053	856-489-8977		nsuglia@fleischerlaw.com	Counsel for Canon Financial Services, Inc.
Florida Attorney General	Ashley Moody, Office of the AG	The Capitol PL-01		Tallahassee	FL	32399-1050				FL Attorney General
Franchise Tax Board	Bankruptcy Section, MS: A-340	PO Box 2952		Sacramento	CA	95812-2952				Franchise Tax Board
Frank Patterson WMCI #13216		7076 Road 55 F		Torrington	WY	82240-7771				Interested Party
GHR General Healthcare Resources	Jessica Glatzer Mason	2250 Hickory Road, Ste. 240		Plymouth Meeting	PA	19462			jmason@foley.com	Top 30 Creditor
Gray Reed & McGraw LLP	Jason S. Brookner, Aaron M. Kaufman, Lydia R. Webb,Amber M. Carson	1300 Post Oak Boulevard, Suite 2000		Houston	TX	77056	713-986-7127	713-986-5966	jbrookner@grayreed.com; akaufman@grayreed.com; lwebb@grayreed.com; acarson@grayreed.com	Counsel for the Debtor and Debtor in Possession
Hackney Odlem & Dardas, PLC	Thomas G. Hackney	10850 E. Traverse Hwy., Ste. 4440		Traverse City	MI	49684	231-642-5026		thackney@hodlawyers.com	Counsel for Dr. Jeffrey Bomber, Dr. Robert David Lacy, Dr. Victoria Hallett, Dr. Rickey Coleman, Donna Marie Rohrs, Dr. Aleatha Denise Reitsma-Mathias, Dr. Charles Stewart Jamsen, and Rosilyn Jindal
Halo Branded Solutions	Scott Schaefer	3182 Momentum Place		Chicago	IL	60689-5331			Scott@schaeferslaw.com	Top 30 Creditor
HCA Health Services of FL	David Tassa	2020 59th Street West		Bradenton	FL	34209-4604			dtassa@kslaw.com	Top 30 Creditor
Highwoods Properties	Ronn Steen	P.O. Box 409355		Atlanta	GA	30384			Ronn.steen@thompsonburton.com	Top 30 Creditor
Internal Revenue Svc	Centralized Insolvency Operation	PO Box 7346		Philadelphia	PA	19101-7346				IRS
Internal Revenue Svc	Centralized Insolvency Operation	2970 Market St	Mail Stop 5 Q30 133	Philadelphia	PA	19104-5016				IRS

Master Service List

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Kansas Attorney General	Kris W Kobach	120 SW 10th Ave, 2nd Fl		Topeka	KS	66612-1597				KS Attorney General
KCC	Darlene S. Calderon	222 N Pacific Coast Highway, Suite 300		El Segundo	CA	90245	781-575-2040		tehuminfo@kccllc.com	Claims and Noticing Agent
Kentucky Attorney General	Daniel Cameron	700 Capitol Ave	Capital Bldg Ste 118	Frankfort	KY	40601				KY Attorney General
Lane & Nach, P.C.	Adam B. Nach	2001 E. Campbell St., #103		Phoenix	AZ	85016			adam.nach@lane-nach.com	Counsel for Henry Snook, Jennifer Power, Aanda Slocum, Linda Floyd, successors and assigns
Latricia Revell		1568 Sterling Place		Brooklyn	NY	11212	929-234-1835		Latriciarevell227@gmail.com	Committee of Unsecured Creditors
Liftforward / Hitachi / Mitsubishi	Mark Magnozzi	P.O. BOX 1880		Minneapolis	MN	55480-1880			mmagnozzi@magnozzilaw.com	Top 30 Creditor
M.E. Heard, Attorney, PLLC	Mary Elizabeth Heard	100 NE Loop 410, Suite 605		San Antonio	TX	78216	210-572-4925		meheard@heardlawfirm.net	Co-Counsel for Adree Edmo
Maryland Attorney General	Anthony G Brown	200 St Paul Pl		Baltimore	MD	21202-2022			oag@oag.state.md.us	MD Attorney General
Maxim Healthcare	Erno Lindner	12558 Collections Center Drive		Chicago	IL	60693			elindner@bakerdonelson.com	Top 30 Creditor
Maxim Healthcare Staffing Services, Inc.	Neil M. Williamson	7227 Lee Deforest Drive		Columbia	MD	21046	410-910-6191		newillia@maximstaffing.com	Committee of Unsecured Creditors
Mehaffy Weber, P.C.	Blake Hamm and Holly Hamm	P.O. Box 16		Beaumont	TX	77704	409-835-5011	409-835-5177	BlakeHamm@MehaffyWeber.com; HollyHamm@MehaffyWeber.com	Counsel for Saint Alphonsus Health System, Inc
Mercy Hospital (MO)	Lisa Manziel	1400 US Highway 61		Festus	MO	63028-4100			info@manziel.com	Top 30 Creditor
Michigan Attorney General	Dana Nessel	PO Box 30212	525 W Ottawa St	Lansing	MI	48909-0212			miag@mi.gov	MI Attorney General
Microsoft	Amy Scoville	P. O. Box 844510		Dallas	TX	75284-4510			amdevi@microsoft.com	Top 30 Creditor
Missouri Attorney General	Andrew Bailey	Supreme Ct Bldg	207 W High St	Jefferson City	MO	65101				MO Attorney General
Munsch Hardt Kopf & Harr, P.C.	John D. Cornwell and Brenda L. Funk	700 Milam Street, Suite 800		Houston	TX	77002-2806	713-222-1470	713-2221475	jcornwell@munsch.com; bfunk@munsch.com	Counsel to State of Idaho, Idaho Department of Corrections, and certain officials or employees of the State of Idaho
Munsch Hardt Kopf & Harr, P.C.	Randall W. Miller	500 N. Akard Street, Suite 3800		Dallas	TX	75201-6659	214-855-7539	214-855-7584	rwmiller@munsch.com	Counsel to State of Idaho, Idaho Department of Corrections, and certain officials or employees of the State of Idaho
Nephrology and Hypertension Associates L.L.P.	Thomas Riley	1205 West Broadway		Columbia	MO	65203		573-449-1787	triley@rsb.com	Top 30 Creditor
New Jersey Attorney General	Matthew J Platkin	Richard J Hughes Justice Complex	25 Market St 8th Fl West Wing	Trenton	NJ	08625				NJ Attorney General
New Mexico Attorney General	Raul Torrez	408 Glisteo St	Villagra Bldg	Santa Fe	NM	87501				NM Attorney General
New York Attorney General	Letitia James Dept. of Law	The Capitol, 2nd Floor		Albany	NY	12224-0341				NY Attorney General
Newman, Kathleen	TGH Litigation LLC, J. Andrew Hirth	28 N. 8th Street, Suite 317		Columbia	MO	65201			andy@tghlitigation.com	Top 30 Creditor
Norton Rose Fulbright	Julie Goodrich Harrison	1301 McKinney	Suite 5100	Houston	TX	77010-3095	713-651-5434		julie.harrison@nortonrosefulbright.com	Counsel to DIP Agent M2 LoanCo, LLC
Norton Rose Fulbright	Kristian W. Gluck	2200 Ross Avenue	Suite 3600	Dallas	TX	75201-7932	214-855-8210		kristian.gluck@nortonrosefulbright.com	Counsel to DIP Agent M2 LoanCo, LLC
Office of the United States Trustee	Ha Minh Nguyen	515 Rusk St Ste 3516		Houston	TX	77002			ha.nguyen@usdoj.gov	Office of the United States Trustee
Osborn Maledon, P.A.	Warren J. Stapleton and Christopher C. Simpson	2929 N. Central Ave, Ste. 2000		Phoenix	AZ	85012	602-640-9000	602-640-9050	wstapleton@omlaw.com; csimpson@omlaw.com	Counsel for Arizona Department of Corrections, Rehabilitation, and Reentry
Pennsylvania Attorney General	Michelle Henry	1600 Strawberry Square, 16th Fl		Harrisburg	PA	17120			press@attorneygeneral.gov	PA Attorney General
Pike County Memorial Hospital	Jonathan Shoener	2305 West Georgia St.		Louisiana	MO	63353			fandblegal@gmail.com	Top 30 Creditor
Rachell Garwood		31956 West Cranston Street		New Haven	MI	48048	586-260-8325		rachellgarwood@yahoo.com	Committee of Unsecured Creditors

Master Service List

CreditorName	CreditorNoticeName	Address1	Address2	City	State	Zip	Phone	Fax	Email	Description
Racine Olson, PLLP	Daniel C. Green	201 E. Center Street	P.O. Box 1391	Pocatello	ID	83204	208-232-6101	208-232-6109	dan@racineolson.com	Counsel for Tehum Care Services, Inc.
Rifkin Law Office	Lori Rifkin	3630 High St. Ste. 18917		Oakland	CA	94619			lrifkin@rifkinlawoffice.com	Top 30 Creditor and Co-Counsel for Adree Edmo
Saint Alphonsus Health System, Inc.	Keely Duke, Stephanie Westermeier	1055 North Curtis Road		Boise	ID	83706-1309	208-367-6325		ked@dukeevett.com; stephanie.westermeier@trinity-health.org	Top 30 Creditor and Committee of Unsecured Creditors
St. Luke's Health System, Ltd.	Wendy Olson, Stoel Rives, LLP and David Barton	190 E. Bannock		Boise	ID	83712-6241	208-493-0560		wendy.olson@stoel.com; bartond@slhs.org	Top 30 Creditor and Committee of Unsecured Creditors
Stinson LLP	Paul B. Lackey	2200 Ross Ave., Suite 2900		Dallas	TX	75201	214-560-2201	214-560-2203	paul.lackey@stinson.com; ed.caldie@stinson.com; phillip.ashfield@stinson.com; nicholas.zluticky@stinson.com	Counsel for the Official Unsecured Creditors' Committee
Stromberg Stock, PLLC	Mark Stromberg	8350 N. Central Expressway, Suite 1225		Dallas	TX	75206	972-458-5353	972-861-5339	mark@strombergstock.com	Counsel for Lone Star Alliance Inc., A Risk Retention Company, a subsidiary of Texas Medical Liability Trust
Stueve Siegel Hanson LLP	Ethan M. Lange	460 Nichols Rd., Suite 200		Kansas City	MO	64112	816-714-7174	816-714-7101	lange@stuevesiegel.com	Counsel for the Curators of the University of Missouri and Capital Region Medical Center
Supplemental Healthcare	Fariha Haider	P.O. Box 27124		Salt Lake City	UT	84127-0124			fhaider@shccares.com	Top 30 Creditor
Tehum Care Services, Inc.	Russell Perry, Chief Restructuring Officer, Ankura Consulting Group, LLC	2021 McKinney Ave., Ste. 340		Dallas	TX	75201			russell.perry@ankura.com	Debtor and Debtor in Possession
Tehum Care Services, Inc.		205 Powell Place, Suite 104		Brentwood	TN	37027				Debtor and Debtor in Possession
Texas Attorney General	Attn Bankruptcy Department	300 W. 15th St		Austin	TX	78701	512-463-2100	512-475-2994	bankruptcytax@oag.texas.gov; communications@oag.texas.gov	TX Attorney General
TN Dept of Revenue	c/o TN Attorney General's Office, Bankruptcy Division	PO Box 20207		Nashville	TN	37202-0207	615-532-8718	615-741-3334	steve.butler@ag.tn.gov	TN Dept of Revenue
Truman Medical Center, Inc. d/b/a University Health	Office of General Counsel, Claire Hillman	2301 Holmes Street		Kansas City	MO	63108			Claire.hillman@uhkc.org	Top 30 Creditor and Committee of Unsecured Creditors
U.S. Department of Justice Office of the U.S. Trustee	Andrew Jimenez	606 N Carancahua St, Ste 1107		Corpus Christi	TX	78401			andrew.jimenez@usdoj.gov	U.S. Department of Justice
US Attorney Southern District of Texas		1000 Louisiana Ste 2300		Houston	TX	77002			usatxs.atty@usdoj.gov	United States Attorney
Vang, Ka et al	c/o Webb Law Group, Lenden Webb	466 W. Fallbrook Ave., #102		Fresno	CA	93711			lwebb@webblawgroup.com	Top 30 Creditor
Virginia Attorney General	Jason Miyares	202 North Ninth St		Richmond	VA	23219				VA Attorney General
White & Case LLP	Samuel P. Hershey	1221 Avenue of the Americas		New York	NY	10020			sam.hershey@whitecase.com	Counsel to YesCare Corp. and CHS TX
WhiteGlove Placement	Linda Markowitz	89 Bartlett Street		Brooklyn	NY	11206			lmarkowitz@whiteglovecare.net	Top 30 Creditor
Willis Towers Watson RMS LLC		29754 Network Place		Chicago	IL	60673-1297				Top 30 Creditor
Wyoming Attorney General	Bridget Hill	200 W 24th St	State Capitol Bldg Rm 123	Cheyenne	WY	82002				WY Attorney General